UNITAID
MID-TERM EVALUATION OF THE HIV-HCV DRUG AFFORDABILITY PROJECT

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FINAL REPORT

Submitted by:

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CEPA

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ACRONYMS AND ABBREVIATIONS

Acronym	Full description
C+	Coalition Plus
CEPA	Cambridge Economic Policy Associates
CL	Compulsory licence
CSO	Civil society organisation
DAA	Direct acting antiviral
FTE	Full-time equivalent
HAP	Hepatitis Advisory Panel
HCV	Hepatitis C virus
HCW	Healthcare workers
IP	Intellectual property
LIC	Low-income country
LMIC	Lower-middle income country
Logframe	Logical framework
M&E	Monitoring & evaluation
MICs	Middle-income countries
MoH	Ministry of health
MPP	Medicines Patent Pool
PegIFN	Pegylated interferon
PLHIV	People living with HIV
PLHCV	People living with HCV
PTE	Part-time equivalent
PWID	People who inject drugs
SDGs	Sustainable Development Goals
ToR	Terms of reference
UMIC	Upper-middle income country
UN	United Nations
VL	Voluntary licence
WHO	World Health Organization

EXECUTIVE SUMMARY

Project background

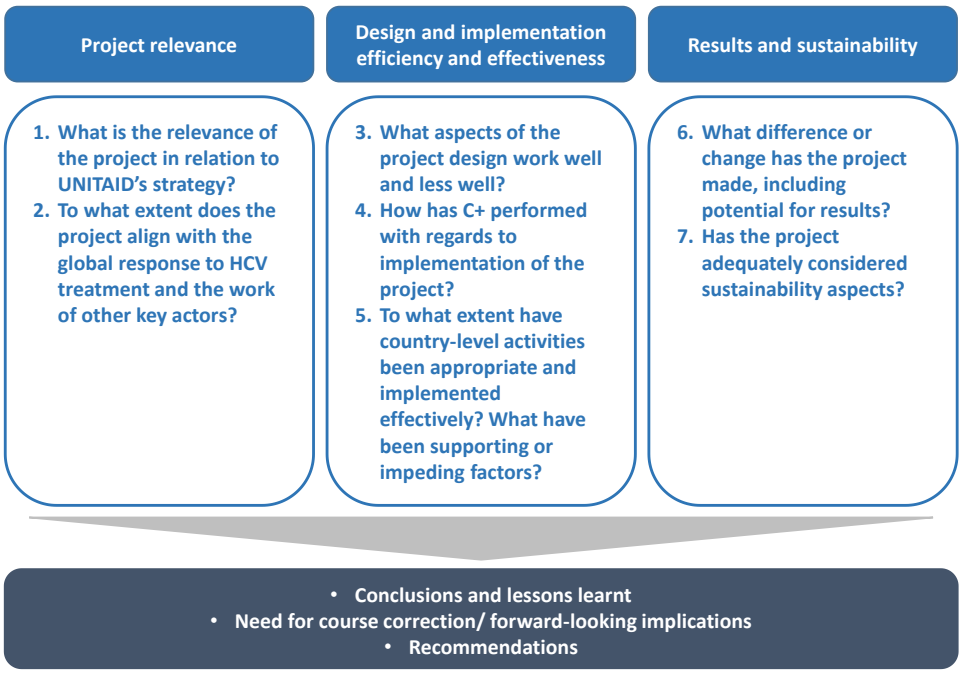
The HIV-HCV Drug Affordability project was approved by the UNITAID Board in May 2014 to improve access to affordable medicines for the hepatitis C virus (HCV). The US$5.23m project focuses on supporting civil society organisations (CSOs) in middle-income countries (MICs) to advocate for better access to direct acting antivirals (DAAs) and mobilise government commitment to implement universal HCV treatment programmes using these more effective drugs, alongside certain global coordinating activities.

The project is being delivered by Coalition Plus (C+) with support from country CSOs, and has been implemented in two phases: Phase 1(a), from May 2015 to April 2016, which focused on establishing the project and building the capacity of C+; and the ongoing Phase 1(b), focusing on a range of global and country activities. As of April 2017, activities have been launched in six countries (Malaysia, Thailand, Morocco, Colombia, Indonesia, India), with activities being planned for Brazil.

Evaluation objectives and methods

The evaluation framework for this mid-term programmatic review is structured around three key dimensions (Figure A), and is based on a desk-based document review and data analysis, consultations with UNITAID, C+ and key global HCV stakeholders and country reviews supported by visits and telephone consultations.

Figure A: Evaluation framework



Key findings by evaluation dimension are presented below, followed by overall conclusions, lessons learnt and recommendations.

Dimension 1: Project relevance

In terms of relevance to UNITAID's mandate, the following was assessed:

- The project has been relevant to both the 2013-16 and 2017-21 strategies, particularly the latter which emphasises UNITAID's work in HIV/HCV co-infection and considers an integrated approach to health. Further, while the project has focused more on HCV as a whole as opposed to solely co-infection, we believe this has been appropriate given its longer-term impact on co-infection.
- While advocacy-based interventions are not core to UNITAID's mandate, the focus on encouraging awareness and commitment aims to support demand generation, which is critical to UNITAID's role in supporting market dynamics.
- The project has focused on MICs rather than low-income countries (LICs) that are also not normally UNITAID's focus. However, advocacy efforts for HCV treatment are most relevant in MICs, given their potential buying power and ability to mobilise the global market for DAAs; plus MICs have often been omitted from recently issued voluntary licences (VLs).

With regards to the project's alignment with the HCV landscape, we note the following:

- The project is much needed in the HCV space, given the limited number of actors and global response, thereby emphasising UNITAID's catalytic role in the global aid architecture.
- Our consultations with the limited HCV actors in the international landscape (including UNITAID grantees such as WHO, MSF and FIND), have emphasised the importance of this project as a much needed intervention. UNITAID grantees have also noted how their project work will be supported through positive results from the C+ grant, by creating greater awareness and commitment for HCV treatment.

Dimension 2: Design and implementation efficiency and effectiveness

Project design and C+ implementation performance

In general, the overall design of the project has worked well, with a phased approach being needed to help build C+ capacity (requiring to hire all full-time staff for this project); country selection being rational and based on relevant selection criteria and assessments; and the mix of global and country activities complementing each other. However, an area of weakness in the project design has been the M&E approach where the logframe does not adequately measure the range of country activities, there is limited clarity on the development of baselines and milestones, and there is inadequate emphasis in measuring intermediate outcomes which is core for an advocacy-based project.

Project implementation has been beset with delays, including most notably with C+ project staff recruitment, completion of Phase 1(a), development of investment cases and the

launch of initial country programmes. Given the two and a half year project timeframe, several of these delays have had significant implications, resulting in limited time for implementation of country activities. As a result, budget spending has been lower than projected, with 2016 total spend US$1.1m less than planned. Although spending rates are starting to increase, C+ estimates 23% of the total budget will not be spent. Global-level activities, while delayed, are being implemented with positive feedback from stakeholder (e.g. HCV partner coordination meetings).

In terms of risk management, while C+ has made some improvements in this area overtime, the overall approach has been relatively weak, with many important risks not being highlighted in initial risk assessments. We assess that greater focus should have been placed on identifying implementation risks within the control of the project.

We assess that the close management approach of C+ by UNITAID during the initial stages of this project was appropriate, given C+ capacity issues. However, this approach has led to high transaction costs for both UNITAID and C+ (recognised as an unsustainable approach for UNITAID). We assess that while UNITAID has since lightened their management of the project with increased confidence in C+ (also with the effective functioning of the Hepatitis Advisory Panel (HAP)), the early close management has set the tone for the relationship between the organisations, and C+ is yet to fully make the concurrent shift towards managing country programmes.

Implementation and performance of country activities

C+ has, for the most part, identified relevant and effective partners, with project support enabling partners to have a dedicated focus on HCV issues. However, partner selection represents a missed opportunity in Thailand, where partner expertise only covers community engagement, with limited expertise (and thereby project focus) on influencing policy makers.[1]

In terms of completion of country activities, by the end of 2016, Malaysia and Colombia had made good progress on the logframe targets relative to other countries. While Thailand and Morocco are on track to achieve some of their targets, select targets are not on track. This is more significant for Thailand, and is largely due to project delays linked to an incorrect bank transfer. For Morocco, these are less significant, relating to activities which are about to start. However, the quantitative M&E indicators used to measure this progress often fail to highlight the true nature of progress made in countries.

We assess progress in implementation of country activities across the following three broad categories:

- **Policy dialogue with key stakeholders** – This is the strongest area of the project, with the most potential for results. In Malaysia, activities are aimed at supporting

[1] We understand C+ are currently bringing on board an additional partner in Thailand to address this issue.

the issuing of a compulsory licence (CL) through educating policy makers on the legalities and implications of this. In Morocco, the focus is on ensuring the National Strategic Plan to fight viral hepatitis is implemented effectively, adequately financed and that barriers to treatment access are removed. Colombia activities include advocacy for the use of magistral drugs. In some cases, external factors have impacted project progression, but approaches have been revised accordingly, highlighting the capabilities and flexibility of partners. However, this activity area is not currently a focus in Thailand, given lack of partner expertise in advocating with policy makers, with questionable effectiveness of the activities that have been included under this category.

- **Community engagement/ empowering** – Despite relatively poor achievement of project indicators for this area, our assessment shows that significant efforts are indeed underway in terms of demand generation to access treatment and empowering communities to advocate for policy change. In Malaysia, partners are working with communities to develop action plans and have developed an advocacy training toolkit. In Thailand, the already established networks of PLHIV are being leveraged to develop support networks for PLHCV. Morocco project activities have focused on enabling prisoners to access HCV testing and treatment. This area has been a key project success, with far more activities geared towards demand creation than anticipated. However, whilst these activities are relevant they are unlikely to achieve significant results within the project timeframe, given their slow time lag for results.
- **Knowledge building –** This includes the development of a number of reports and papers relevant in each country, which will be a key legacy of the project. These include a set of policy briefing papers developed in both Malaysia and Colombia, which have been used to advocate with policy makers, and development of investment cases is underway in Morocco and Indonesia, which is expected to be highly pertinent to present a clear economic argument for HCV investment and a comprehensive report on HCV in Malaysia. However, the extent to which this body of evidence is accompanied by strategic plans on dissemination/ how they will have impact varies by country.

Country partners were generally positive of the management and coordination role played by C+, including on the technical support provided by C+ and the effectiveness of a dedicated Country Partnerships Manager for each country. However, there have also been challenges with C+'s management, with concerns raised over the amount of time required to develop the project, the balance of time and resources to manage the project as not being proportionate to the size of the project and issues over the lack of autonomy or flexibility within the project for partners to make reasonable budget changes. This inflexibility has been presented as a UNITAID requirement, despite UNITAID outlining that

country-specific changes that do not result in overall budget changes do not require approval, thereby meriting more flexible management approaches going forward.

Dimension 3: Results and sustainability

The overall approach to achieve the project goal and outcomes is appropriate and the project has laid a solid foundation for ensuring that advocacy efforts can contribute to improving access to HCV treatment. However, there was general agreement that the goal and outcomes are unlikely to be achieved within the project timeframe, requiring a longer-term commitment.

Nevertheless, the project has already seen a range of significant results, with stakeholders noting that without the project activities would have been considerably less organised, more piecemeal and of lower priority. Key results include:

- **Influencing policy makers,** with the most tangible results having been in Malaysia where the government has committed to assessing the possibility of issuing a CL and the project has created a "champion" Parliamentarian who is leading on HCV advocacy efforts. In both Morocco and Colombia, there is significant potential for results in this area, with limited potential in Thailand given the lack of focus on policy makers.
- **Increasing capacity and knowledge of civil society**, with results across all country projects. In Malaysia, advocacy to the Muslim Council has led to direct funding to purchase DAAs through buyers' clubs. In Colombia, patient organisations are discussing HCV-related issues with the media and local health authorities.
- **Increasing coordination between CSOs,** with a CSO platform established in Morocco and the bringing together of partners in Malaysia who rarely worked together.

While HCV is starting to be recognised as an important issue within the international community, donor funding remains limited. Further, the activities of the project rely considerably on the funding from UNITAID for ensuring that they continue. Given these issues, we assess that there is risk of the progress generated thus far being diluted without ongoing advocacy work after the conclusion of the grant in December 2017.

Conclusions, lessons learned and recommendations

The project is much valued and seen as being very relevant by all stakeholders consulted, particularly given the low levels of attention to HCV globally. Project implementation has been beset by delays from the very start, highlighting the appropriateness of the phased approach given initial capacity issues with C+. However, global and country activities that have been implemented have largely been positive, with some notable results already achieved. For example, the project has contributed to a CL being considered in Malaysia, increased overall awareness of HCV issues in Colombia, supported the development of an

implementation plan for the National Strategic Plan to fight viral hepatitis in Morocco and increased awareness by civil society of HCV issues in Thailand.

Whilst the project is moving in the right direction, achieving the overall goal and outcomes within the project timeframe is unlikely, particularly given the short project time remaining. However, the multi-pronged approach of the project in terms of targeting policymakers, empowering communities and building knowledge is viewed as enabling results to be achieved over the longer time horizon. Therefore evidence from the project to date suggests that not continuing activities beyond December 2017 will dilute the momentum achieved to date and retard progress and opportunities for policy change and community empowerment.

Based on our findings, we provide the following **recommendations**:

1. Consider extending the project, should progress continue in a similar manner and country contexts remain unchanged.[2] Given the significant investments made for this project, it would represent a missed opportunity for this project not to bear sustainable results.
2. Re-evaluate the approach in Thailand to ensure project results can be achieved. Without revisions to the Thailand programme, a continued use of UNITAID resources represent ineffective use.[3]
3. Refine the overall monitoring and reporting approach of the project, to include incorporating a theory of change that considers how project activities, outputs, intermediate outcomes, outcomes and impacts are interrelated. The monitoring and evaluation (M&E) framework should be redefined to include additional measurements that capture intermediate outcomes. Further, greater focus should be placed on qualitative reporting of activities and outcomes.
4. Develop a more robust risk management framework that places greater emphasis on immediate risks within the control of the project.
5. Clearly define country project management arrangements to allow for greater country flexibility, whilst retaining accountability.
6. Ensure all project activities maximise their strategic impact, through reviewing the extent to which each activity will reach the intended impact. For example, the project is developing a body of evidence on HCV issues and it will be critical that activities are included to maximise the impact of this information, such as through a targeted dissemination strategy or a plan for policy change.

[2] We highlight that our recommendation is from the programmatic and country impact perspective, and UNITAID should also consider the findings of the operational review whilst deliberating project extension.

[3] Although we understand C+ are currently bringing on board an additional partner in Thailand, a critical review of the overall approach in Thailand will still be required to ensure relevance to overall project approach and results.

7. Improve project links across countries and with project global activities. For example, there is potential to learn lessons from Colombia's ability to raise awareness among key populations; project countries could also establish a mentoring relationship with non-project countries, including increased engagement with the HAP.
8. Leverage opportunity to raise HCV profile through project coordination with other global events/ associations.

1. INTRODUCTION AND EVALUATION APPROACH

Cambridge Economic Policy Associates (CEPA) has been appointed by UNITAID to conduct a mid-term review of the "HIV-HCV Drug Affordability" project, under UNITAID's long-term agreement on evaluations with CEPA. This draft report presents our evaluation findings, conclusions and recommendations, following a first round of comments by UNITAID.

This introduction section provides a brief background to the project (Section 1.1), the evaluation objectives, framework and methodology (Section 1.2) and the structure of the rest of the report (Section 1.3).

1.1. Project background

Improving access to hepatitis C virus (HCV) treatment formed part of UNITAID's 2013-16 Strategy, particularly in relation to HIV-HCV co-infection, and increasing the affordability of treatment was explicitly included as an exploratory intervention. UNITAID has continued this commitment in its 2017-21 Strategy, which includes a commitment to improve drug affordability. In response to this and following a call for proposals, Coalition Plus (C+) submitted a concept note for a US$15.2m project in 2013. This initial proposal was structured in three phases for C+ to: (i) form an HCV alliance across eleven middle income countries (MICs); (ii) to negotiate lower prices for HCV drugs through voluntary licences (VLs), or issue compulsory licences (CLs) if VLs could not be negotiated; and (iii) enable rapid market entry for generic products.

In May 2014 the UNITAID Board approved the first stage of the project for a US$5.23m ceiling focusing on building commitment for increased HCV treatment in individual countries. Following concerns from UNITAID during the initial project development over the viability of forming such an alliance and the ability of C+ to deliver a project of this size, the concept of an alliance was removed. While discussion on subsequent phases has continued, these were required to receive additional Board approval and made contingent on the success of earlier phases.

The final agreed project has been set-up in two phases, namely Phase 1(a) and Phase 1(b).

- **Phase 1(a)**, from May 2015 to February 2016 (and later extended to April 2016), focused on ensuring the project was started effectively and that C+ was in a good position to deliver the project in the target countries. In particular, this involved hiring key staff, establishing the Hepatitis Advisory Panel (HAP), undertaking initial country visits and signing partnership contracts for Thailand and Malaysia and

finalising grant documents for Phase 1(b), namely the project plan, logframe and budget.[4]

- **Phase 1(b)**, from May 2016 to December 2017, is focused on establishing country partnerships with civil society organisations (CSOs) and implementing country-specific advocacy and awareness campaigns, supplemented with the development of certain market intelligence reports (including investment cases) to feed into the national campaigns, and sharing of lessons through the HAP meetings, convening coordination mechanisms for relevant stakeholders and developing a lessons learned report.

Table 1.1 below outlines the Phase 1(b) project goal, outcomes and outputs, as set out in the February 2017 logframe.

Table 1.1: Project goal, outcomes and outputs

Result level	Description
Goal	Contribute to universal access to HCV care in low and middle income countries
Outcome	Improved government commitments, national protocols, budgets, and/or policies for HCV treatment access in target countries for hepatitis and HIV co-infected patients
Outputs	1. HCV movement network are established or strengthened in target countries 2. Awareness and education campaigns are performed in target countries 3. Lessons learned are widely disseminated

The roll-out of the country programmes is split in three waves, as set out in Table 1.2 below.[5] C+ has established partnerships with local CSOs to implement the country programmes, also detailed in the table below.

Table 1.2: Countries included, contracting dates and CSO partners

Country (Wave)	Contracting dates	CSO partners (lead partner in bold)
Malaysia (Wave 1)	July 2016	**TWN**, MAC, MTAAG+
Thailand (Wave 1)	September 2016	**TTAG**, Ozone
Morocco (Wave 2)	September 2016	**ALCS**, ITPC-MENA *(ITPC-MENA until February 2017 only)*
Colombia (Wave 2)	October 2016	**Ifarma**, Mision Salud, Liga Sida[6]

[4] It was originally agreed (upon grant signature) that Wave 1 country CSO contracts would be signed during Phase 1(a). However, in view of delays encountered during Phase 1(a), UNITAID stipulated (upon signature of the grant extension) that no contracts could be signed with partners until after Phase 1(b) had been approved to avoid assuming uncertain legal responsibilities. UNITAID did request C+ to submit packages for Malaysia and Thailand by the end of February and March 2016 respectively to ensure contracts could be signed as soon as Phase 1(b) was approved.

[5] Given wider developments and the feasibility of rolling out the programme in some countries, the project is now focusing on seven as opposed to eleven countries that were initially envisaged.

Country (Wave)	Contracting dates	CSO partners (lead partner in bold)
Indonesia (Wave 2)	January 2017	**PKNI**, Spirtia Foundation
India (Wave 3)	April 2017	**DNP+**, CoNE Manipur
Brazil (Wave 3) – to be confirmed	n/a	n/a

1.2. Evaluation objectives, framework and methodology

1.2.1. Evaluation objectives

Based on the Terms of Reference (ToR) and discussions with the UNITAID Secretariat, this is a "programmatic evaluation" of the project, which will be complemented by an "operational review" that is being commissioned alongside. The objective of the programmatic evaluation is to review the implementation progress being made by the project and emerging results (actual and potential) being achieved. Review of C+ capacity and operations is not included within the scope of this evaluation.

1.2.2. Evaluation framework

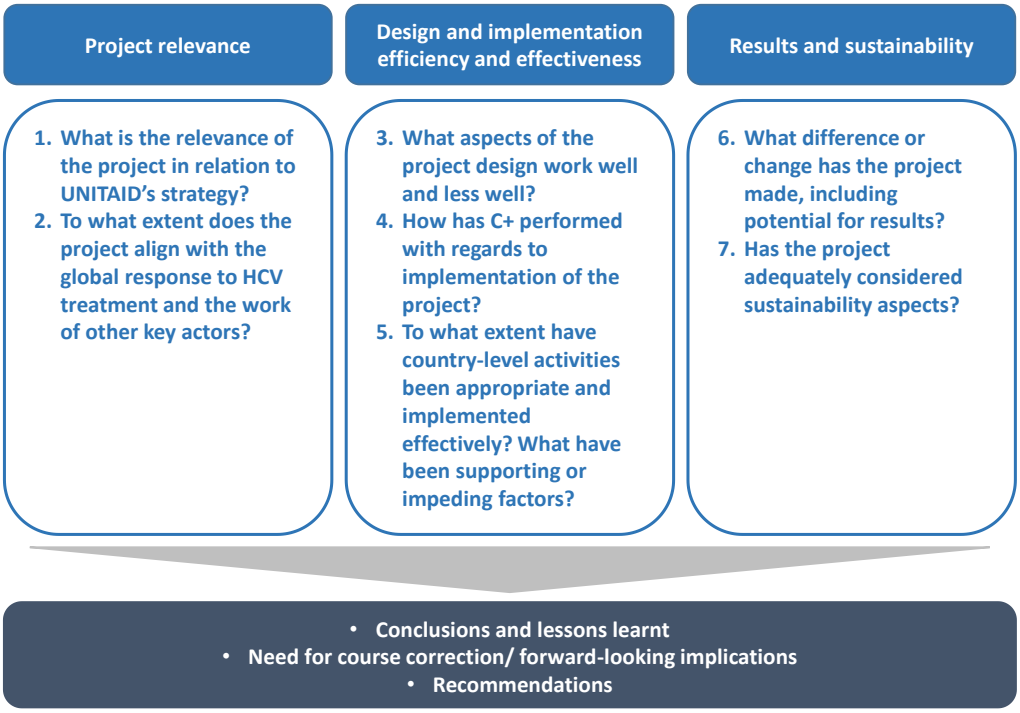
Figure 1.1 presents the evaluation framework, drawing on the series of evaluation questions included in the ToR and the focus areas indicated by the UNITAID Secretariat. It has been structured as three core and inter-related dimensions of:

- **Project relevance** – focusing on the alignment of the project objectives and scope in relation to UNITAID's strategy and mandate, as well as the global response to HCV treatment and the role of other actors.
- **Design and implementation efficiency and effectiveness** – encompassing an assessment of the project design and implementation experience in terms of C+'s performance and the country-level activities and progress.
- **Results and sustainability** – examining the impact that the project is achieving to date as well as *potential* impact, plus the extent to which "sustainability drivers" have been adequately considered.

The assessment across these dimensions informs the evaluation conclusions and lessons learnt, as well as forward looking implications and recommendations.

[6] Mision Salud and Liga Sida do not have a formal contractual relationship with C+, but are supporting Ifarma with project activities.

Figure 1.1: Evaluation framework



1.2.3. Evaluation methods and limitations

The key methods employed for the evaluation include: (i) desk-based review of documents and data; (ii) consultations with project stakeholders; and (iii) country reviews through country visits and telephone consultations. Details of each of the evaluation methods are provided below.

- **Desk-based document review and data analysis:** Key reference documents include UNITAID's strategy documents, grant agreements and project plans, annual and semi-annual reports, disbursements letters and country assessment reports. Data analysis includes a basic analysis of how the project is performing in relation to its logframe targets as well as the budget. Annex A provides a list of references.
- **Stakeholder consultations:** This includes in-person meetings with the UNITAID Secretariat and C+, as well as telephone meetings with key stakeholders in the HCV landscape including the World Health Organization (WHO), other UNITAID HCV grantees (Médecins Sans Frontières (MSF) and Foundation for Innovative New Diagnostics (FIND)), etc. Annexes B and C provide the list of consultees and the interview guides.
- **Country reviews:** Three visits to countries where programme activities have begun namely, Thailand, Malaysia and Morocco, were undertaken (two-three days per country by two team members). Consultations were conducted with the CSO partners, government officials, other CSOs and other relevant partners in country. Given budget limitations, telephone consultations with a selection of stakeholders in

Colombia were also conducted. Annex C provides the list of country consultees and interview guides, with country case studies included in Annex E.

Key limitations of the evaluation include potential bias in stakeholder selection for country consultations as these were suggested by project implementers, lack of access to policymakers to support certain country case studies and challenge in attributing any results to the project per se (given confounding factors and time lags for results from advocacy interventions).

1.3. Structure of the report

The report is structured as follows: Sections 2-4 present analysis and findings across each of the three evaluation dimensions of relevance, design and implementation efficiency and effectiveness and results and sustainability. Section 5 presents lessons learned and recommendations.

The main report is supported by the following annexes:

- Annex A presents the bibliography/ list of references;
- Annex B presents the list of inception phase consultations and interview guides;
- Annex C presents the list of core phase consultations and interview guides;
- Annex D presents a summary of key project delays;
- Annex E presents the country case studies for Malaysia, Thailand, Morocco and Colombia;
- Annex F summarises the risks identified by C+ throughout the project.

2. PROJECT RELEVANCE

The first dimension on project relevance focuses on the relevance of the project in relation to: (i) UNITAID's strategy; and (ii) the global response to HCV treatment. These aspects are considered in turn below.

2.1. Relevance to UNITAID strategy

1. What is the relevance of the project in relation to UNITAID's strategy?

We consider the relevance of the project in relation to UNITAID's strategy and mandate by examining the prioritisation of the project objectives, activity focus and country coverage.

Project objectives in relation to UNITAID strategy

As noted in Section 1.1, the project spans two successive UNITAID strategies i.e. the previous 2013-16 Strategy and the current 2017-21 Strategy. The 2013-16 Strategy, under which the project was approved, has the mission of contributing to scaling-up "*access to treatment for HIV/AIDS, malaria and TB…by leveraging price reductions for drugs*" alongside the strategic objective of supporting medicines to "*…improve the treatment of HIV/AIDS and co-infections such as viral hepatitis*" (Strategic Objective 3). The strategy recognises the HIV-HCV co-infection burden and the market shortcomings at that time in relation to pegylated interferon (PegIFN)/ribavirin, with the plan for exploratory interventions that aim to make affordable treatment regimens available. As such, the project, with its goal of contributing to improving universal access to HCV care in low and middle income countries, was directly aligned with the UNITAID strategy. However, the Strategy also notes that as per UNITAID's Constitution, the fight against HIV/AIDS, malaria and TB remains the organisation's main priority, with the noted caution of not diverting resources away from this priority.[7]

The current 2017-21 Strategy appears to better emphasise UNITAID's work in HIV co-infections. The Strategy notes that UNITAID *"maintains its commitment"* to HIV/AIDS and co-infections with HCV, but also emphasises this commitment further than before by recognising the need for an "*integrated approach"* to health that addresses the needs of people affected by more than one disease.[8] As such, we view the emphasis on HIV-HCV co-infections, and thereby the relevance of the project, as having heightened under the current Strategy.

[7] UNITAID 2013-16 Strategy, April 2013, page 65.

[8] Since the development and adoption of the 2013-16 strategy, the HCV treatment market has changed drastically with direct acting antivirals (DAAs) coming onto the market. As such, while barriers associated with the efficacy of PegIFN have been largely addressed with the availability of new medicines, affordability remains a key issue for increasing treatment in countries.

An issue however, is that UNITAID's mandate is focused on HIV-HCV co-infections (and in fact we note that the project title and goal has been 'force-fit' to reflect this prioritisation), in actual practice, the project focus, in terms of the nature and design of activities, is on HCV as a whole (i.e. including HCV mono infections). Given the limited policy and financial attention dedicated to HCV in project countries, we view this holistic project approach as appropriate and more likely to impact the co-infection issue in the longer term, thus linking back to UNITAID's priorities.

Activity focus – advocacy

The design or activity focus of the project has evolved over time to a stand-alone focus on advocacy in countries, which is not core to UNITAID's mandate and operations. In fact, the HIV-HCV co-infection strategic narrative (August 2016), that maps the priority challenges to be addressed by UNITAID specifically notes the exclusion of several objectives/ activities that are within the scope of the project such as "lack of awareness of status", "lack of awareness of HCV and risk factors" and "insufficient political advocacy". More generally, it is well-noted that this project is a 'first of its kind' advocacy-focused project in UNITAID's portfolio.[9]

That said, the nature of advocacy interventions has been specifically aimed at encouraging awareness and commitment for HCV treatment, thereby supporting demand generation which is critical to UNITAID's role on impacting market dynamics. Given the early stages of the HCV market situation, with low levels of HCV awareness (including lack of awareness of the relatively newly introduced DAAs), advocacy efforts for generating demand are particularly relevant and important. Indeed, the project is expected to contribute towards several areas for intervention identified in the strategic narrative, such as on area 2 on finding innovative ways to unlock funding for HCV and area 3 on increasing affordability and adaptability of HCV medicines.

Country focus – MICs

Finally, we note that the project focuses on MICs, as compared to UNITAID's priority on low-income countries (LICs). For example, the UNITAID Constitution notes that no more than 10% of UNITAID's resources dedicated to purchase commodities will be allocated to lower-middle income countries (LMICs) and no more than 5% to upper-middle income countries (UMICs). Whilst this project does not purchase commodities, it also does not imply that the project contradicts UNITAID's Constitution as there is indeed provision to support these countries – just a lower degree of emphasis.

Further, the 'logic model' or 'theory of change' of the project, as emphasised by UNITAID and C+, is that advocacy efforts in the MICs are needed as they have greater buying power,

[9] The Proposal Review Committee (PRC) report states that this is "new terrain for UNITAID".

as well as health systems that are more capable of scaling up, than the LICs (particularly relevant in the case of HCV given the limited donor landscape). Thus, MICs have a greater potential to mobilise the market for DAAs, with the eventual outcome of reduced prices for both MICs and LICs (i.e. ultimately also benefitting UNITAID's priority country focus). The state of the HCV market, with patents in a number of MICs and thereby continued monopolies, presents the rationale for the country focus of the project. Specifically, the VLs issued by both Gilead and BMS for sofosbuvir and daclatasvir respectively, do not cover a number of MICs implying that the cost of such drugs remains at unaffordable levels for widespread use.

Summary findings:

The project is relevant and well-aligned with UNITAID's strategy, more so with the new 2017-21 Strategy that emphasises the commitment to HIV-HCV co-infection and considers an integrated approach to health. The project's approach to HCV as a whole (as compared to co-infections alone), activity focus on advocacy for policy change and focus on MICs (rather than LICs) is different from UNITAID's *standard* project approach, but responds to what is needed in the HCV context.

2.2. Alignment with global HCV response

2. To what extent does the project align with the global response to HCV treatment and the work of other key actors?

Despite picking up momentum since 2010, the global response to HCV has been and remains very limited. In this context, UNITAID's role in funding and supporting HCV through this project (and UNITAID's broader portfolio of HCV projects) is much needed, and plays well with its intended catalytic and "front runner" role in the global aid architecture.

Key developments in the global response to HCV have included: (i) the first and second World Health Assembly resolutions on viral hepatitis (2010 and 2014); (ii) the WHO framework on viral hepatitis prevention and control (2012); (iii) the WHO Global Health Sector Strategy on Viral Hepatitis 2016-21; and (iv) the inclusion of hepatitis related goals within the UN Sustainable Development Goals (SDGs). These developments highlight the burden of HCV (and viral hepatitis more generally), the issue of lack of awareness and need to improve screening, especially in vulnerable population groups such as people who inject drugs (PWID) and the need to improve access to quality and affordable diagnosis and treatment – all aspects that resonate with the advocacy efforts under the current project. The 2016-21 WHO Strategy highlights the importance of advocacy efforts in several areas (e.g. to support information for action, awareness of the public health importance of viral hepatitis, and to mobilise country commitment and resources) as a means to achieve the ambitious specific targets on reduced infections and deaths and overall goal of eliminating viral hepatitis as a major public health threat by 2030. In general, the project is therefore well aligned and seeks to be an important contribution to the overall global response to HCV.

Our consultations with the limited HCV actors in the international landscape (including UNITAID grantees such as WHO, MSF and FIND), have emphasised the importance of this project as a much needed intervention. UNITAID grantees have also noted how their project work will be supported through positive results from the C+ grant, by creating greater awareness and commitment for HCV treatment. Partners noted that supporting CSO-based advocacy is important for holding governments accountable for their activities, and is something that other partners, particularly those providing technical support, are less able to do. This is particularly needed in HCV relative to other diseases (particularly HIV) where advocacy support is relatively strong and well-established. Others, such as the Medicines Patent Pool (MPP), have noted the complementary action of their work with the C+ projects towards improving market access and affordability (especially given C+'s focus on several countries that are not covered by the voluntary licenses that have been issued to date). Indeed, UNITAID's 'theory of change' for its HCV portfolio highlights the interlinkages and complementary nature of its various projects in HCV.

Further, the project is coordinating with WHO, including through ongoing discussions regarding the investment cases for the project (although WHO has emphasised the need for consistency in methodology with their work on developing investment cases as well as the need for early engagement between the two parties). More generally, the project envisages support for a 'coordination space', which is a coordination mechanism amongst the various actors, with its first intervenors meeting held in March 2017. Participants have noted the much needed role for this activity, given the limited actors in this area.

Summary findings:

The project is much needed in the HCV space, given the limited number of actors and global response, thereby emphasising UNITAID's catalytic role in the global aid architecture. The project will serve as a contribution to the global goals for HCV.

3. DESIGN AND IMPLEMENTATION EFFICIENCY AND EFFECTIVENESS

The second dimension of the evaluation framework focuses on three questions on the efficacy and efficiency of: (i) the project design; (ii) implementation by C+; and (iii) implementation and progress of country-level activities. We consider each of these aspects in turn below.

3.1. Project design

3. What aspects of the project design work well and less well?

We consider below the extent to which the final agreed project design (recognising changes from the initial C+ proposal) has worked well, considering key elements including: (i) the phased approach; (ii) country selection; (iii) focus and range of project activities; and (iv) the monitoring and evaluation (M&E) approach.

3.1.1. Phased approach

As noted in Section 1.1, the project has been split into two phases: an initial planning and detailed design phase (Phase 1(a)), and a second phase that has involved the full roll-out of the project in the selected countries as well as undertaking global activities (Phase 1(b)). Further, there has been a phased approach to country work, with commencement of country planning and activities in three waves.

In essence, both of these phased approaches were needed, as C+ was a small organisation and needed to build capacity for effective delivery (also recognising that there are limited actors in the HCV field in general). In particular:

- At headquarters level, the phased approach was needed given all seven full-time equivalent (FTE) project positions needed to be recruited, three during Phase 1(a) and four during Phase 1(b), in addition to the three part-time equivalent (PTE) existing management positions.[10]
- For the country work, the phased approach was needed to enable C+ to develop capacity and experience to prepare the relevant country packages (including country assessment, partner selection, work plans and budgets). We understand that initial country packages entailed several iterations between UNITAID and C+ as compared to later packages. We also understand that the wave approach allowed C+ to learn lessons which facilitated the later "on-boarding" of countries.[11]

[10] FTE positions: Project Manager, 3 CSO Partnership Managers, IP and Access to Medicines Policy Officer, Admin & Logistics Officer and Finance Officer. PTE positions: C+'s Deputy Director, Head of Advocacy, Media Officer and Finance Manager.

[11] For example, the initial CSO selection meetings were conducted with multiple partners. On reflection, C+ noted that while useful, multi-stakeholder meetings were less productive than holding bilateral meetings with

As such, these phased approaches enabled better preparation and capacity-building for project implementation.

3.1.2. Country selection

As noted in Section 1.1, while some key MICs have been included in the recently issued VLs for key DAAs (such as India and Indonesia), a number of MICs have been excluded and therefore are still required to pay very high prices. Further, in a number of MICs, treatment programmes continue to be driven by PegIFN and have limited coverage as universal treatment programmes with DAAs are not being implemented. As a result, actual treatment of HCV remains limited. As such, the project has rightly focused on a key set of MICs in order to improve the affordability of DAAs, and with the aim of increasing government commitment to rolling out universal HCV treatment programmes, in line with the WHO Global Health Sector Strategy on Viral Hepatitis 2016-21. Whilst some of the HCV stakeholders consulted for this review indicated that advocacy efforts for LICs is also much-needed, they recognised that this would be a much "harder nut to crack" given lack of donor support for HCV and limited fiscal space in these countries, as well as agreeing with the rationale to catalyse the market in MICs in order to increase volumes and therefore reduce prices.

We review the C+ methodology for country selection as largely sensible, being based on a mix of country need and potential success factors, including having adequate health systems and budgets to offer and roll-out universal and free at point of care HCV treatment; a large patient base required to rapidly absorb high volumes of HCV drugs; a positive environment for improving access to medicines, evident from previous issues of CLs or a commitment to reducing the cost of medicines, in addition to local production of generic versions of DAAs; and C+ having strong partnerships in the country or the ability to create partnerships with organisations active in the HCV space that were therefore likely to be effective in delivering the project's objectives.

The initial list of identified countries has been modified and reduced over the course of the project for a range of relevant reasons, including difficulties for international organisations to operate (China), graduation to high income status by the World Bank (Argentina) and limited HCV prevalence (Ecuador). Whilst we note a difference of opinion in whether the removal of China and Argentina represent a missed opportunity, we view the final selection of countries as being highly relevant in relation to the project objectives. It was also recognised that having fewer countries means that C+ can prioritise and focus on these country programmes with less risk of becoming over-stretched once all countries are on-board.

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partners, given that in multi-stakeholder meetings discussions centred more on what budgets would be allocated to different partners, rather than on the most relevant activities or best placed partners.

3.1.3. Focus and range of project activities

This section presents comments on project activities from the design perspective, with the implementation of project activities discussed in Sections 3.2 and 3.3.

The project includes both global and country activities, with the budget comprising mostly staff and operational/ activity costs. Of the total budget:

- There is a 42:58 split between the global and country budget. Whilst this global-country split makes sense given C+ is managing the country network and delivering global-level activities, it is noted that the budget for country-level work comprises only around half of the grant value.
- For both the global and country budgets, costs have been split relatively evenly between staff and operational/ activity costs. Given, the advocacy nature of the project, it is reasonable for staff costs to be roughly equal to activity costs.

For the global activities, a number of useful activities have been included, such as:

- The creation and meetings of the HAP, which was needed given the broad range of experience the members bring and the technical/ capacity support C+ needed, particularly at the start of the project.[12]
- The country investment cases and the investment case model, which will help mobilise support for HCV treatment in the given countries; and selecting Indonesia and Morocco for the country investment cases seems reasonable given that they currently have access to affordable DAAs.
- Global coordination meetings, including for country partners allowing them to be updated on wider project developments, and other stakeholder groups, which may be viewed useful in the context of the limited actors and coordination in the HCV space.

For the country activities, the focus on both direct advocacy with policy makers and increasing knowledge and capacity of civil society to advocate for improving HCV treatment seems appropriate in most programmes, with the mix varying according to the country context. However, there are some variances by project country e.g. concerns were raised by some stakeholders in Thailand that despite it being difficult for CSOs to advocate directly with government the project has limited focus on this type of advocacy and going forward would like to see more efforts to advocate directly with government. Further, there has been limited emphasis on cross-learning or working between countries (discussed in Section 4.1).

[12] While we note that establishing the HAP has not explicitly been defined as a global project activity per se, given that HAP support has been provided at the global level and for simplicity we have included it under global activities.

3.1.4. M&E approach

Developing a robust M&E framework that effectively identifies and tracks the outputs, outcomes and impacts for an advocacy-based intervention is particularly challenging given the "intangible" and "upstream" nature of advocacy activities, the time lags to translate into results and the existence of multiple confounding factors (e.g. enabling environment). Notwithstanding this, C+ (in collaboration with UNITAID) have developed a useful logical framework (logframe), particularly in terms of defining the outcomes and goal. However, we note the following issues with the logframe:

- **Inadequate measurement of country-level activities:** Only one of the three logframe outputs (output 2) measures the direct results of the project activities, when this is the most significant component of the project. Within output 2, several project activities are not measured such as the work on developing policy briefs and other knowledge/ information products.
- **Inappropriate aggregation of several country indicators:** Whilst the 2016 annual reporting by C+ presents the disaggregated country indicators only, there is reference to an aggregated project target which we view as misleading. The approach followed in the logframe is for individual country outputs being aggregated quantitatively for project-level outputs. This masks country variations – not only in terms of the progress achieved but also the significance of the progress given different country and activity contexts (e.g. 50% aggregate progress can represent 5/10 policy makers reached in a large country along with 20/40 policy makers reached in a small country). Further, output 2.1 aggregates a number of different type of incomparable events (e.g. PLWHIV events are very different from health worker events in terms of their intended results).
- **Lack of clarity in development of baselines and targets:** The country-level output indicators – and specifically output 2.2 on results in relation to policy advocacy activities – may be viewed as subjectively designed, based on the experience of C+ and the country CSOs. While the targets may indeed be appropriate, it is not possible to objectively verify these without a detailed mapping of policy makers or other information that has not been provided.
- **Emphasis of results tracking on completion of activities rather than measuring their benefit or utility:** For example output 1.1, 2.1, and 2.3 focus on the completion of activities included in the work plan, planned events and planned mass media campaigns respectively. While these indicators are useful to assess, we do not view these as adequate given they do not provide information on whether activities were viewed useful to the recipients (e.g. as feasible through feedback forms, surveys,

etc., which have not been incorporated in the M&E framework for the project).[13] Indeed in our assessment we find more significant progress made than that measured by these quantitative indicators (e.g. with regards to the policy dialogue work).

- **Lack of consideration of "intermediate" outcomes:** This may include aspects noted above in terms of recipient views on the benefits of an activity, or also other aspects that form the pathway to the noted outcomes, such as community empowerment, improved knowledge, etc., requiring both quantitative (e.g. survey-based) and qualitative measurement. Our approach to reviewing the results of the project considers these, as presented in Section 4.1.

We comment that an appropriately designed M&E framework for an advocacy project cannot exclusively rely on quantitative indicators, and as such qualitative information is also needed to provide more insight and depth. While C+ have been providing updates to UNITAID on the project's progress through annual and semi-annual narrative reports, these reports often fail to include details on *how* activities have contributed to project outcomes.

Summary findings:

In general, the design of the project has worked well, with a phased approach being needed to help build C+ capacity, country selection being rational and the mix of global and country activities complementing each other. However, an area of weakness in the project design has been the M&E approach.

3.2. C+ implementation performance

4. How has C+ performed with regards to implementation of the project?

We examine project implementation performance by C+ in terms of: (i) implementation of global-level activities; (ii) timeliness of the project as a whole; (iii) budget spend; and (iv) risk management. These aspects consider the roles and responsibilities of C+ within the project, with country-level activities being discussed in Section 3.3. We also consider the engagement between UNITAID and C+.

The review does not consider C+ capacity and operational management in detail, as this is covered under a separately commissioned operational review.

3.2.1. Implementation of global activities

As noted in Section 3.1.3, global activities have mainly focused around the following:

[13] We understand that C+ have monitored partner and intervenor meetings through feedback forms. However, this is not systematically conducted for country-level activities.

- **Convening the HAP –** The HAP was established in December 2015 to advise C+ on project areas, such as country selection and focus of global activities. Members have engaged with C+ both formally through biannual meetings and on an ad-hoc basis by telephone and email. C+ has noted that having this strategic input was highly valued, and having buy-in and support from such influential figures has added credibility to the project. Our consultations also noted that the level of engagement from HAP members has been sufficient and well-received. This is also supported by progress on the logframe, showing most HAP members were present at meetings in 2016.
- **Convening coordination mechanisms –** C+ initially planned for separate meetings with HCV intervenors[14], activists, forecasters and regulators. However, forecaster and regulator meetings have subsequently been removed from the project given they were deemed of lesser importance than the investment cases (see next point). C+ has also organised coordination meetings between in-country CSOs to share experiences and learn lessons. The activist and project coordination meetings were carried out in July and September 2016, while the intervenor meeting took place in March 2017. Stakeholders noted that meetings have been worthwhile for understanding the work being implemented by this project. In addition, given the limited number of actors in the HCV space there is a real need for coordination, with this activity being deemed as highly valuable by all stakeholders.
- **Market intelligence reports –** Although several market intelligence reports were planned, the project has been re-focused so that more funds could be allocated to the investment cases, while the forecasting and regulatory barriers reports have been removed. Since this reallocation, C+ hired a consultant to develop the investment cases in February 2017. While we cannot comment on the quality of the investment cases at this time, many stakeholders noted this refocusing as being an appropriate approach. The CL Feasibility Report is also planned for 2017, although the resources dedicated to this are expected to be considerably smaller than the investment cases.

Thus, in general, C+ has performed well with regards to the global-level activities. In particular, both the HAP and global coordination meetings have been noted as being useful and important project additions. However, some key activities have been delayed, particularly the investment cases (see next section). Nevertheless, the ability of C+ to refocus activities, rather than allocate budget to activities that were later deemed to be of less importance, demonstrates an ability to prioritise activities when needed.

[14] According to the 2016 Annual Report, intervenors are defined as organisations with projects and investments in the HCV treatment space, including WHO, MSF, CHAI, FIND, MPP, DNDi, the World Hepatitis Alliance, OSF, TAG and the South Centre.

3.2.2. Timeliness

Project implementation has been beset by a range of delays, with some being longer and having a more significant impact than others, although most delays have resulted in reducing the length of time the project can carry out activities within each country. Annex D provides a full description of project delays, with key delays including:

- Additional two months required to complete Phase 1(a), thereby lengthening the 'start-up' phase, which, we understand, created considerable transaction costs for both UNITAID and C+.
- Recruiting C+ staff took longer than planned. In Phase 1(a), difficulties were encountered recruiting the Project Manager, due to a lack of suitable candidates, which required bringing on board a recruitment agency to support the process. Whilst this only slightly delayed the recruitment, there was then a subsequent delay in recruiting the third position during that phase and further delays of up to six months to recruit the remaining team members during Phase 1(b). These delays had a considerable impact on other project activities, including establishing the HAP. Further, delays in building an operational C+ project team combined with the need to finalise partnership on-boarding documents during Phase 1(a) created a missed opportunity in Thailand. These delays resulted in a lack of clarity in processes and project approach, which resulted in key partners not being brought in to the project due to lack of confidence in C+ (discussed in Section 3.3).
- Investment case development began in February 2017, nine months later than planned, representing a risk to their potential impact on country activities if a clear plan on how these are to be taken forward and by whom is not developed, given they will only be completed at the end of the project.
- Starting activities in the initial countries, Malaysia and Thailand, was delayed by four and nine months respectively. However, country delays have been reducing over time with later country programmes commencing with less of a delay/ ahead of schedule.

While some of these delays may have related to C+ capacity issues (e.g. length of time required to finalise documentation for Malaysia and Thailand "on-boarding"). More generally however, we view the planned timeframes as unrealistic especially given that advocacy interventions are slow to realise results – e.g. the activities in Brazil and India will be implemented over a period of only 6-7 months. As such, the project presents a situation where substantial time has been spent "starting-up" with limited time for actual activity implementation given the two and a half year project timeframe. This has key implications for the results and sustainability of the project, as discussed in Section 4.

3.2.3. Budget spend

Of a total budget ceiling of US$5.23m, overall project spend by the end of 2016 was slightly over US$1m (19%) and by the end of 2017 C+ expect to spend a total of US$4.04m (77%).

For Phase 1(a), according to the C+ Annual Report 2016, total expenditure against the initial budget was US$372k, or 3% lower than the initial budget. This indicates that spending was in line with the developments of the project, with expenditure being lower than anticipated during the earlier months and then increasing during the later months.

For Phase 1(b), by the end of December 2016 overall spend was US$632k, 49% of which was allocated to HQ staff costs. This is considerably lower than the US$1.7m originally budgeted for this period, and is largely due to fewer countries being included in the project, HQ consultancy activities being postponed, decreasing or scaling down coordination activities and earlier delays in recruitment.

The approved budget for 2017 is for a total of US$3.03m, 19% of which is allocated for HQ staff costs, representing a significant shift in staffing to project costs from 2016.

While it has generally been slower than initially envisaged, project spending is starting to increase in line with the increase in project activity. However, as noted there is a projected underspend of 23% of the total budget. This largely reflects a number of countries being removed from the project, plus fewer funds for staff costs and activities due to initial delays.

3.2.4. Risk management approach

C+'s approach to risk management was identified as a key area of concern by UNITAID during the initial stages of the project, given that no formal risk management processes were in place. Following these initial concerns, C+ has taken steps to articulate specific risks as part of its project planning, including in project plans for Phase 1(a) and Phase 1(b), and as part of its annual and semi-annual reports. In spite of this process, we understand that UNITAID has flagged further concerns following the 2016 semi-annual report submission, and requested submission of a risk assessment in between the formal reporting requirements and have also agreed to further discuss the risk assessment with C+ following this evaluation. Annex F provides a summary of the risks identified by C+ to date.

Whilst a full assessment of risk is outside the scope of this evaluation, given it is covered in the operational review, we provide an overview of risk in relation to programme implementation. In particular, our assessment is that while there have been improvements in C+'s approach to risk management over time, overall, the approach to risk management has been relatively weak. For example, some important risks were not highlighted in C+'s risk assessments despite some having been identified by UNITAID in an internal risk assessment, including (with some of these already occurring in practice):

- C+'s small size and lack of experience in managing grants of this size;
- Partners dropping out of the project;

- Implementation risks associated with in-country CSOs being unable to perform activities, such as being unable to access key policy makers or coordinating community groups due to external factors; and
- Administrative risks that have a direct impact on the project's activities, such as delays to in-country CSOs receiving funding.

Of the risks that were identified in project documents, several were wider, macroeconomic risks that seem less relevant given that they could not be influenced by the project, including wider reductions in drug prices and changes in WHO's strategy. We assess that greater focus should have been placed on identifying implementation risks within the project's control that would have a direct impact on the project's activities and intended results, such as those highlighted above. We also assess that the mitigation approaches proposed have not been considered in detail, with some left as open ended strategies and others not being adequate.

3.2.5. Engagement between UNITAID and C+

Engagement between UNITAID and C+ has been extensive, with UNITAID having tightly managed the project, closely guiding and reviewing project implementation. We view this engagement as being needed on account of C+'s initial low project capacity (particularly noting that all FTE staff had to be recruited during the project period) and C+'s lack of experience in managing a grant of this size. We also view this management approach being the result of the project being UNITAID's first advocacy project (and the need to closely manage the project given some of the tensions highlighted in Section 2.1 on relevance of the project to UNITAID's strategy and mandate).

However, we understand that over the course of the project and as the capacity of C+ has increased, UNITAID has lightened their management approach. Whilst we view this changing style of management by UNITAID as being appropriate (although note that C+ capacity assessment is outside the scope of this review and will be covered by the operational review), the overall approach has not been without challenges, including high transaction costs for:

- the UNITAID Secretariat, noted as being greater than for other UNITAID projects, which draws into question the sustainability of such an approach; and
- C+, also given their continued approach to requesting approval/ informing UNITAID of relatively minor changes, which they view as being "good management practice" although noting that this is not contractually required (e.g. informing UNITAID of event date changes and requesting approval to amend country partner budgets, neither of which are contractually required).

We assess that the initial close management approach has, to some degree, set the tone for the continued relationship between UNITAID and C+. Whilst UNITAID have altered their

management style, reflecting increased confidence in C+'s capacity, C+ have not made a concurrent shift towards this more flexible management style over the course of the project. It is unclear why C+ have retained the same approach, given we understand that UNITAID have communicated that this is not required, although we note the strong incentives for C+ of proving their management capacity to ensure a continuation of funding. This has resulted in some inefficiencies in country programme management (as discussed in Section 3.3.3).

Summary findings:

- Project global-level activities have been well-received, albeit delayed. More significant have been the delays for the country programmes (Thailand in particular). Whilst country programmes are becoming more timely, they will have limited time for implementation given the two and a half year grant timeframe, with concomitant implications for results.
- There is scope to improve the risk management approach adopted by the project.
- The relatively close management approach by UNITAID has supported capacity building for C+ but also implied high transaction costs.

3.3. Implementation and performance of country activities

5. To what extent have country-level activities been appropriate and implemented effectively? What have been supporting or impeding factors?

This evaluation question considers project country-level activities and presents analysis for each of the case study countries (Malaysia, Morocco, Thailand and, to a lesser extent, Colombia) on:[15]

- the appropriateness of country partner selection (Section 3.3.1);
- implementation of country-level activities, extent to which planned outputs have been achieved and progress against project indicators (Section 3.3.2); and
- an assessment of the efficacy of the engagement between C+ and country partners (Section 3.3.3).

3.3.1. Selection of country partners

Table 1.2 in the introduction section presents the list of project partners by country.

We understand that during initial country visits, C+ met with a range of CSOs to identify the most relevant partners and activities. Partners were identified through C+'s network of country contacts and recommendations provided by HAP members. Given the project objectives span advocating to policy makers and target populations (e.g. PWID, health

[15] As agreed, a country visit was not undertaken for Colombia, rather consultations were held with three key stakeholders.

workers and people living with HIV and people living with HCV (PLHIV-PLHCV)), relevant partners would require this range of expertise (i.e. both high-level policy engagement and grassroots expertise).

Our assessment of the appropriateness of country partner selection is based on a review of partner expertise across the range of project objectives, prior experience/ proven results in these areas and credibility in country, amongst other factors. Our view is that C+ has, for the most part, been able to identify relevant and effective partners. However, there have been some variations by country, with partner selection working particularly well in Malaysia and Colombia, facing some issues in Morocco and representing a missed opportunity in Thailand.

- **In Malaysia**, the three selected partners (Third World Network (TWN), Malaysian AIDS Council (MAC), Positive Malaysia Treatment Access and Advocacy Group (MTAAG+)) are particularly relevant for the project, offering a broad spectrum of experience and expertise. TWN provides expertise on intellectual property (IP) issues and has previous experience of advocating for policy change; MAC provides a strong network to PLHIV and is well-respected by the Ministry of Health (MoH); and MTAAG+ brings experience of empowering alliances amongst PWID.
- **In Thailand**, C+ encountered some difficulties in recruiting partners, with the final selection representing a missed opportunity. C+ initially reached out to a broad range of partners, including, amongst others, AIDS Access Foundation (AAF), one of the leading Thai experts on IP and trade negotiations, with a reported ability to influence policy makers through established relationships and an organisation already active on HCV advocacy, as well as the Thai AIDS Treatment Action Group (TTAG), a grassroots organisation having worked on HCV issues for several years. However, stakeholders noted that C+ were relatively slow to respond to clarifications, did not have a sufficient number of staff at the time of project development, were unclear on the planned project approach in Thailand and there was a general concern over the significant amount of project management for a relatively small grant. AAF were thus unclear on the objectives of the work. This, combined with other factors (such as availability of other funding sources), meant that AAF decided not to join the project. Several stakeholders reported that this organisation would have been the most relevant lead partner.

  C+ therefore signed a contract with TTAG and Ozone, an organisation with an established network of PWID. Whilst these partners are strong in community empowerment, they lack experience in advocating directly with policy makers and have not been involved in relevant activities currently underway in Thailand, including challenging Gilead's patent request or direct price negotiations with policy makers. We understand that C+ is currently in early discussions to bring an additional global-level technical support partner, which, given their presence in Thailand, is

expected to have a positive effect in terms of capacity building of Thai project partners.

- **In Morocco,** the two identified partners (Association de Lutte Contre le Sida (ALCS) and International Treatment Preparedness Coalition – Middle-East and North Africa (ITPC-MENA)) represent the leading national experts in relevant project areas. ALCS brings almost 30 years of HIV advocacy experience, as well as leading more recent national HCV efforts, and ITPC-MENA brings IP/ access to medicines expertise and community-led research. They are viewed by several country stakeholders as being particularly relevant to implement the project. This was also shown by the relevance and clarity of activities designed for the project, far clearer than in other countries.

  We understand that ALCS noted their ability to implement the project alone, but ITPC-MENA was included at the request of C+ due to expertise on IP issues. However, at the end of February 2017, ITPC-MENA decided, in full agreement with ALCS, to withdraw from the project. This was partly in order to focus on other work, given the large amount of time required to manage the project (further discussed in Section 3.3.3), but also due to the tight project deadlines which were deemed to be more efficiently met through one partner working alone.

- **In Colombia,** C+ identified Fundacion Ifarma (Ifarma), one of the leading Colombian organisations working on access, use and quality of medicines. In addition, Mision Salud, a CSO focused on issues associated with access to medicines, and Liga Sida, a community-based organisation with 25 years of HIV experience, support Ifarma on an informal basis, reflecting a history of joint collaboration, thereby bringing the full range of comprehensive expertise required for the project. C+ decided not to formally engage the other CSOs, given the existing arrangements between project partners.

The majority of country CSOs have some experience with HCV, and where this was not the case, have substantial experience in HIV, allowing them to transfer key learnings from HIV and reinforcing the linkages between HCV and HIV. For Colombia, the fact that C+ was able to identify and leverage existing partner relationships has been positive for the project.

3.3.2. Progress on country activities

Progress in terms of the management of country programmes is measured by the first output indicator (O1.1), which reports on progress against activities/ targets/ milestones in each country workplan. By the end of 2016, three of the four countries had exceeded, met or almost met milestones, whereas Thailand was not on track (Table 3.2).

Table 3.2: Country progress against output indicator 1.1 (traffic-light coding to reflect progress)

Indicator	Country	2016 milestone	Results at end 2016
Indicator O1.1: % annual	Malaysia	5/7	Milestone met (5/5)

Indicator	Country	2016 milestone	Results at end 2016
activities/targets/milestones as defined in the annual country workplan that is achieved.	Thailand	6/8	Milestone not achieved (3/6)
	Morocco	7/10	Milestone almost met (6/7)
	Colombia	4/6	Milestone exceeded (6/4)

In terms of progress of project activities, whilst noting these differ across countries (being based on the specific context in the country), we assess these across the three broad categories (Figure 3.1).[16]

Figure 3.1: Country activity categories and indicative examples

We note that activities targeted towards health workers (Indicator O2.1) are not captured in these categories presented in Figure 3.1. Only Colombia and Malaysia have targets for this, with Colombia having implemented three regional forums aimed at doctors and health workers to discuss HCV issues (drug prices, steps towards issuing a CL and magistral drugs), and Malaysia not yet reporting progress towards this target. Generally, this has not been a key focus area of the project and details, where available, are provided in the country case studies included in Annex E.

Annual project progress reports provide details on whether activities were completed and any changes from the planned activity design. Analysis is presented here for each category in terms of relevance of the activity and implementation progress.

Policy dialogue with key stakeholders

Progress against this first activity area, engagement with key policy makers, is measured against output indicator 2.2. Table 3.3 shows that by the end of 2016, no country had met this milestone, although Malaysia had made significant progress.

[16] Based on the project plan for Phase 1(b), we presented a fourth type of advocacy activity in the Inception Report – public mobilisation – however do not present this here separately as there are a small number of activities only in this area, and most of these tie in with the work on community mobilisation (i.e. category (ii)).

Table 3.3: Country progress against output indicator 2.2 (traffic-light coding to reflect progress)

Indicator	Country	2016 milestone	Results at end 2016
Indicator O2.2: % of relevant policy makers that had at least one targeted meeting/workshop per country	Malaysia	32/66	Milestone almost met (26/32)
	Thailand	1/2	Milestone not achieved (0/1)
	Morocco	25/85	Milestone not achieved (10/25)
	Colombia	6/22	Milestone not achieved (3/6)

However, our view is that this quantitative assessment masks the actual extent of progress achieved. Given the expertise of implementing partners in three of the four countries (Colombia, Malaysia and Morocco) on advocating for policy change relating to IP and access to affordable medicines, **this first activity area is in fact viewed as the strongest area of the project**, with the most potential for results.

Chosen activities are relevant to the country context, focusing on the following areas:

- **In Malaysia**, activities are aimed at issuing a CL through educating policy makers on the legalities and implications of this, as well as the need to do so.
- **In Morocco**, given that generics are already produced in-country (albeit at a much higher price than Indian/ Egyptian generics) and that a national hepatitis strategy has been developed (although is waiting the final signature of the newly re-elected Minister of Health), advocacy activities focus on ensuring the strategy is implemented effectively, adequately financed and that barriers to treatment access are removed.
- **In Colombia**, building on Ifarma's application for a declaration of public interest for HCV in November 2015, advocacy efforts have been targeted at key institutions in government. This includes an activity targeting the Colombian Patent Office, which will include producing briefing papers on access to DAAs and the use of magistral drugs. The country programme also includes plans to hold extensive work with parliamentarians and MoH promoting the use of generics.

Whilst it is **difficult to assess whether the most relevant policy makers have been targeted for each specific activity**, given the lack of a comprehensive stakeholder analysis (which was not included in detail in "on-boarding" documents and was out of the scope of this evaluation to conduct), those identified by partners appear to be a logical fit for the project aim (as also confirmed through our discussions with other stakeholders in country). In particular, Malaysian partners have built a strong relationship with one Parliamentarian who is already a strong advocate on affordability of cancer drugs. The interest and activities of this "champion" are therefore being leveraged to include HCV drugs. This approach has brought solid results, with the Parliamentarian receiving a written commitment from the Minister of Health to issue a CL for HCV. Malaysian partners were also able to engage with the Minister of Health at the World Health Assembly in May 2016 (i.e. prior to the project

formally starting) so that they could discuss HCV treatment in a more open and focused manner than what is possible in the country.

In some cases, **external factors have impacted project progression, but approaches have been revised accordingly**, highlighting the capabilities and flexibility of partners. Both Morocco and Malaysia have been beset by delays in this policy dialogue aspect of the project due to a lack of government for eight months following elections and government priorities focused towards election campaigning, respectively. Nevertheless, activities have continued, albeit slightly amended or reduced, for example:

- **In Malaysia**, the planned parliamentary roundtable on medicine pricing was reduced in size. However, partners arranged for the Deputy Minister of Health to chair this meeting, significantly increasing the importance accorded and potential impact.
- **In Morocco**, a parliamentary seminar was planned to raise awareness on HCV, although has been delayed due to the prolonged government changes. This activity will now focus on advocating for a dedicated budget line for HCV and to lift barriers for key populations accessing treatment, namely the homeless and PWID whose lack of paperwork creates a barrier to healthcare.

However, given the partner choice in **Thailand**, whose expertise is in community mobilisation rather than advocating directly to policy makers, advocacy activities aimed at developing policy dialogue with government are marginal. For example, one activity included advocating to policy makers at the National AIDS Conference in March 2017 in Bangkok. However, this referred to a community group petitioning outside the conference and a small group entering the conference to present a letter to a representative from the Department of Disease Control. Whilst this was reported in the conference daily briefing, it is unclear how influential such an activity is likely to be. Furthermore, project partners expressed concerns around the project approach of advocating directly to policy makers. The advocacy approach taken by both TTAG and Ozone is to empower communities to advocate for themselves, rather than advocating directly to policymakers. However, the effectiveness of such an approach is questionable, not only on account of the low credibility of affected groups with government, but also the potential for results within this project timeframe. Given the range of Thai partners with demonstrated expertise in advocating to policy makers, this activity area represents a significant missed opportunity in Thailand and it is unlikely that major results will be achieved during the project lifetime.

Community engagement/ empowering

Progress against this second activity area is measured through output indicator 2.1, which tracks the number of events organised across the three target groups of drug users, health workers and PLHIV-PLHCV. Table 3.4 shows that by the end of 2016, most activities were behind schedule.

Table 3.4: Country progress against output indicators 2.1 (traffic-light coding to reflect progress)[17]

Country	Indicator completed/exceeded	Indicator partially achieved (>40% of milestone)	Indicator not on track (<40% of milestone)
Malaysia	• Drug user events • PLHIV-PLHCV events		• Health worker events
Thailand		• Drug user events	• PLHIV-PLHCV events
Morocco			• Drug user events
Colombia		• Health worker events	

However, we do not view this M&E approach as appropriate as some indicators had no entries or were less than the target due to the activities being less relevant for the country programme during the reporting period. For example in Morocco, drug user events were not seen as necessary given the low numbers in country and in Colombia, fewer health worker events were needed than initially targeted.

A more qualitative assessment shows **significant efforts are indeed underway in raising community awareness on HCV issues**, both in terms of demand generation to access treatment and empowering communities to advocate for policy change, particularly around drug pricing. However, whilst these activities are relevant to achieving the project goals, **it is unlikely that this approach will achieve any significant results within the project timeframe**. All stakeholders reported that this approach required much longer for tangible results.

Activities and details on implementation performance relating to empowering community voices and building demand include:

- **In Malaysia**, MTAAG+ is working with communities to develop action plans to raise awareness amongst target populations and have developed an advocacy training toolkit to support these community groups. In addition, work is continuing with the Parliamentarian (noted above) to build alliances between HIV, HCV and cancer patients to have a stronger voice on accessing affordable medicines, and MAC is planning a film festival to raise awareness of HCV issues in the general public.
- **In Thailand**, Ozone is leveraging their well-established networks for PLHIV, to develop support networks for PLHCV, with three sites already operational. However, only one meeting was planned for each group, drawing into question the effectiveness and sustainability of such a network. TTAG have therefore requested a budget amendment to use savings due to delayed project start in order to provide

[17] The UNIPRO data recorded N/A for indicator O2.1 (drug user event and PLHIV-PLHCV) for Morocco and Colombia.

additional support to establishing these groups, but this has not been approved by C+.

A further planned activity was to train communities on IP and access to medicines. However, to date this activity has focused on building the capacity/ knowledge of the two implementing partners. Given the lack of existing knowledge amongst staff, it is unlikely that this activity will lead to the intended results within the project timeframe. Whilst the activity is relevant to the country context, this does not leverage the expertise of the implementing partners. Either a different partner would be required to delivery this activity or more relevant activities should have been designed with respect to partner expertise.

- **In Morocco**, ALCS have built on the strong relationship they have developed with the prison authorities where they already conducted testing for HIV, and have been able to include HCV testing in some prisons. In addition, one of the activities planned to be implemented in 2017 by ITPC-MENA was the creation of community advisory boards to bring together community activists with Moroccan and non-Moroccan generic manufacturers (e.g. the Egyptian manufacturer Pharco) in order to encourage competition and thereby reduce the price of generics. Whilst ITPC-MENA plan to continue this activity (with funding from the Robert Carr Fund), it will no longer be a formal part of the project. In terms of raising awareness in the general public on HCV, a radio advert is ready for transmission, with contracts currently being signed with different radio stations, and a website is currently being designed to share a broad range of information on HCV.
- **In Colombia**, this aspect has been one of the key project successes to date, with far more activities geared towards demand created than anticipated, given the increased number of community groups requesting information and briefing materials. This has followed initial workshops held by Ifarma with several key CSOs in Bogota, who in turn discussed the project with local CSOs as well as other key stakeholders. As a result, local organisations have requested more information relating to HCV, while Ifarma is planning to visit several regions to build further awareness.

In general therefore, a number of context-specific and innovative activities are being implemented in each of the countries, with emerging successes in Malaysia, Morocco and Colombia, albeit with some challenges in Thailand. Whilst these activities are slower to bear fruit (as noted above), they are covering a range of relevant community groups, with an emphasis on improving access to both diagnosis and treatment.

Knowledge building

The project is also enabling a body of evidence to be developed, which will represent a key project legacy. Whilst all the papers and reports being prepared seem to be relevant to each

country context, the extent to which these are accompanied by a strategic plan for policy change/ action and dissemination differs by country/ activity. The logframe does not include an indicator to track progress in this area. We present the in terms of progress:

- **In Malaysia**, TWN has produced a set of four policy briefing papers.[18] These have been widely disseminated to policy makers and have been used during policy dialogue activities described above. In addition, the paper relating to patents and high DAA prices was turned into a letter to policy makers. We understand that these advocacy letters signed by a range of organisations and community groups are a powerful tool in Malaysia, with Ministry officials reporting to project partners that such letters receive the attention of senior officials and responses are required. MAC have also prepared a comprehensive report on HCV, aimed at policy makers, health professionals and civil society. However, given the lengthy nature of the document only part of this will be translated and there are currently no plans to develop targeted policy papers. Whilst this will be an important resource for those already interested in HCV, it is unclear the extent to which it will be effective at raising awareness of and interest in HCV issues across other stakeholders (given its length, multiple audience focus, unclear plans for dissemination, etc.).
- **In Thailand**, a range papers are planned although not yet finalised. These include a HCV situation paper, drawing on the experience of a range of stakeholders. However, we understand that the plan is to only speak with a small number of stakeholders in the Bangkok area, so it is unlikely to be fully representative or comprehensive.
- **In Morocco**, an investment case is currently underway and expected to be completed before the end of the project, with several stakeholders noting the benefits this is likely to bring in terms of presenting a clear economic argument for investment, thereby changing policies and providing evidence to support a HCV-dedicated budget line. This is particularly timely, given the government will be developing new budgets, as well as for the current Global Fund concept note development process and is expected to provide a favourable environment for HCV investment. Further activities were planned to be completed by ITPC-MENA, including a benchmarking study on DAA pricing and a monitoring report on HCV context. Both of these will be completed, albeit outside of the project. ALCS will instead conduct a benchmarking study on diagnostic pricing and develop a situation report on HCV inclusion in harm reduction activities, both of which were viewed as highly relevant by stakeholders.

[18] Briefing paper titles are: (i) Access to Hepatitis C medicines; (ii) Compulsory licensing/ Government use licenses; (iii) Thailand's Compulsory licenses experience; and (iv) Patents and high DAA prices in Malaysia.

- **In Colombia**, knowledge building efforts have primarily been focused around Ifarma's umbrella campaign "Regalate un Minuto" (Give yourself a minute), under which Ifarma has produced a range of information material that will be used throughout project implementation. In addition, Ifarma has produced two policy briefs for the Colombian IP Office, which focus on the economic impact of HCV drug prices and the IP status of key HCV drugs in Colombia, Chile and Brazil.

Overall country activity progress

In terms of overall progress on country activities, we therefore note:

- Malaysia and Colombia have made good progress on the logframe targets relative to other countries.
- On the other hand, while Thailand and Morocco are on track to achieve some of their targets, select targets are not on track. This is more significant for Thailand, and is largely due to project delays linked to an incorrect bank transfer. For Morocco, these are less significant given the delays relate to media pieces that are waiting final approval and policymaker meetings have been delayed due to a lack of government.

3.3.3. C+ and country partner engagement

This final section of the second review dimension analyses the efficacy of the engagement between C+ and the country partners, in terms of what is working well and where there have been challenges. Further country-specific details are provided in Annex E.

Partners were **generally positive** of the management and coordination role played by C+, noting specifically on the:

- utility of technical support provided by C+, including developing advocacy materials and discussing the most appropriate project activities;
- effectiveness of a dedicated Country Partnerships Manager (CPM) for each country;
- appropriateness of country work plan and budget design, determined between country partners and C+, before final approval from UNITAID, thus best leveraging contextual knowledge; and
- tailored logframes by country and clarity of reporting templates.[19]

However, partners also noted a **range of challenges** with regards to C+'s management role.

In terms of the start-up phase, whilst Wave 1 countries experienced some teething problems (Malaysia and Thailand), largely linked to low staff resourcing levels, Wave 2 partners (Colombia and Morocco) reported more positively on the project development in terms of clarity of objectives and processes. However, a common theme from implementing

[19] Country CSO reporting to C+ is on the same frequency as C+ reporting to UNITAID (i.e. twice a year).

partners was concerns raised over the amount of time required to develop the project, referring to lengthy discussions and detailed planning process, which partners referred to as being particularly long and time-consuming, with one noting that "*designing this project has taken the longest time in our organisation's history"*. However, the timeframe between initial country visits and launching programmes has improved, with Malaysia and Thailand taking nine and eleven months respectively, while for Colombia this took five months. Further, each country assessment report was required to be approved by UNITAID, while instituted because of low C+ capacity, has added to the timelines.

In terms of ongoing project management, all partners considered the balance of time and resources to manage the project as not being proportionate to the size of the project. For example, the average annual total country budget for 2017 is US$166k, which is then further divided amongst partners. Some stakeholders also stated that this focus on project management reduced the amount of time that they could spend on project activities, which was also given as one of the reasons for ITPC-MENA's withdrawal from the project.

We note that in an advocacy-based project there is a high chance of needing to change activities, given a number of external factors outside of project control, and as such there is a need for more flexibility in project management. We understand that UNITAID have provided C+ with this flexibility over the management of sub-grants to country partners, requiring only to be informed should overall total budget categories change. Whilst there are several examples of C+ providing flexibility for some partners, in general we assess that C+ have applied a fairly rigid management style with country partners, notably requiring the pre-approval of activities or budget change (irrespective of the size/ significance). C+ provided the following reasons for this:

- Several country partners have limited capacity to manage projects and therefore need to be closely managed.
- This is a "good learning experience" for some country partners in terms of building their capacity to manage larger grants from donors.
- Desire to retain project funds for a potential project extension, rather than increase the project spend, also given concerns over partner absorption capacity.

Whilst there is indeed good justification for C+ to closely manage country partners, country partners understand this to be a UNITAID *requirement* (with country partner viewing UNITAID as a fairly inflexible donor). Further, C+ are requesting UNITAID to approve these changes, which has led to project delays. In several cases financial savings due to late recruitment of staff are not being used for project activities, despite requests from country implementers and UNITAID stating a preference to invest more in countries. Specific examples include:

- In Thailand, partners have recognised that activities have not been effectively designed in order to achieve project aims. For example, only one meeting has been

planned for each support group and national advocacy meetings have been planned without any pre-meetings for groups to agree on common messages. To address these issues, partners requested to realign budget savings due to the late starting of the project, providing a plan of activities and budget annexed to the Annual Report. C+ have not approved this change, stating that TTAG have not followed the correct procedures, that partners do not have the capacity to absorb additional funds and the additional activities requested were outside of project scope. However, this has meant that the approach to empowering support groups has not been modified to address the concerns that project targets will not be reached.

- In Colombia, Ifarma noted they were planning to submit a budget amendment request to meet the increased community demand, given the need for Ifarma to produce additional materials, using savings from travel to cover these costs. However, Ifarma noted that similar requests had previously taken up to a month to approve (which is relatively long in the context of the short time period for this project).

Therefore, whilst the engagement between C+ and country partners is generally working well, with C+ adding value in some areas, there are also a range of management issues, largely budget related, which will need further consideration for the remainder of the project.

Summary findings:

Country partner selection has been relevant and effective in Malaysia and Colombia, faced some issues in Morocco and represented a missed opportunity in Thailand.

Country-level activity implementation and progress is generally working well, particularly for Malaysia and Colombia, but also Morocco, albeit with some challenges for Thailand.

- Activities relating to policy dialogue represent the strongest area of the project, particularly for Malaysia, Colombia and Morocco.
- Significant efforts are also underway with regards to community engagement/ empowering, although it is unlikely that these activities will achieve results within the project timeframe given their nature.
- The project is also enabling a body of evidence to be developed, which will represent a key project legacy, although the extent to which these are accompanied by a strategic plan for policy change/ action and dissemination differs by country/ activity.

Partners were generally positive of the management and coordination role played by C+, including on the technical support provided by C+ and the effectiveness of a dedicated Country Partnerships Manager for each country. However, there have also been challenges with C+'s management, with concerns raised over the amount of time required to develop the project, the balance of time and resources to manage the project as not being proportionate to the size of the project and issues over the lack of autonomy or flexibility within the project for some partners to make budget changes.

4. RESULTS AND SUSTAINABILITY

The final dimension considers the longer term results of the project as detailed below.

4.1. Actual/ potential impact

6. What difference or change has the project made, including potential for results?

This question focuses on the project's wider impact to date and the potential for the project to have a significant impact in the future, as well as the project's "added value".

4.1.1. Project results and potential for results

As noted in Section 1.1, the project's goal is to "contribute to universal access to HCV care in low and middle income countries", and its outcome is to have "improved government commitment, protocols, budgets and/ or policies for HCV treatment access in project countries". While indicators that measure these are not expected to have been achieved to date, assessing the extent to which these have been achieved and their potential for achieving results forms a key part of this evaluation.

The project goal indicator is for one additional country to launch a universal treatment HCV programme. However, there was general agreement from both country and global stakeholders that this **goal-level indicator is unlikely to be achieved within the project's timeframe**, and many noting that, whilst the project approach is appropriate to contributing towards this goal, the timeframe is not sufficient given it is likely to be at least two to three years before effective and accessible treatment programmes are made available.

Progress achieved by end 2016 against the purpose-level indicators is presented in Table 4.1, with Thailand being the only country to not meet the 2016 milestone, despite having the lowest target. Both Malaysia and Morocco were able to exceed targets relating to policymakers, which is of particular note given overall project delays in both countries relating to access to Parliamentarians, therefore reflecting the strength of these CSO partners.

Table 4.1: Progress against purpose-level indicators (traffic-light coding to reflect progress)[20]

Indicator	Country	2016 milestone	Results at end 2016
Indicator P1: % policymakers expressing official support for CSO demands per country	Colombia	3/18	Milestone achieved (3/3)
	Malaysia	2/10	Milestone exceeded (7/2)
	Morocco	3/19	Milestone exceeded (9/3)
	Thailand	1/2	Milestone not achieved

[20] Indicator P3: # of countries introducing investments into DAAs, has not been included given that no data were provided for this.

Indicator	Country	2016 milestone	Results at end 2016
			(0/1)
Indicator P2: Number & name of countries that have HCV treatment guidelines recommending DAAs included in public health policies	Colombia & Indonesia	0/7	Milestone exceeded (2/0), although achieved prior to project start and therefore cannot be attributed to the project.

As discussed in Section 3.1.4, we do not view this M&E approach as adequate, and instead propose a more detailed review of the pathways to change or "intermediate outcomes", supported by a qualitative assessment based on our country case studies.

We consider the broad categories of activities described in Section 3.3 and their results:

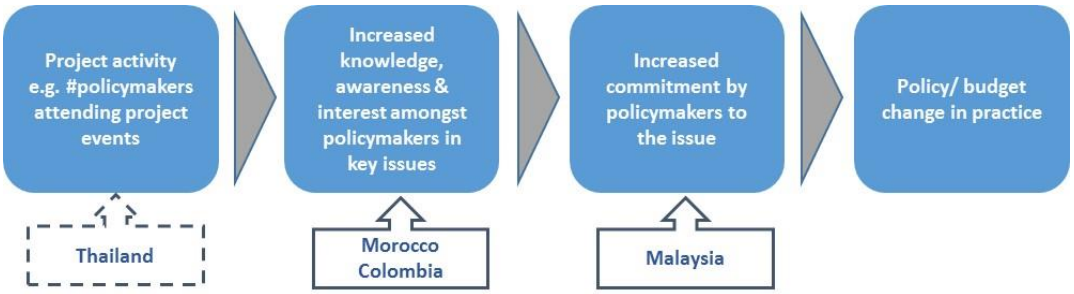
- Policy dialogue with key stakeholders, resulting in increased awareness/ interest and commitment from policy makers.
- Community engagement/ empowering, resulting in greater knowledge and capacity of civil society for HCV.
- Knowledge building activities, contributing to the above-described results
- All of the above activities more generally resulting in increased coordination between CSOs and creation of a CSO movement for HCV.

We consider these progressions of results in detail below, also reflecting on where the different project countries might be within the chain of results. Further details regarding the results in each country are provided in Annex E.

Increased awareness/ interest and commitment from policy makers

Figure 4.1 presents an indicative logic chain of results for policy dialogue activities (for simplicity, presented as linear and without reference to external factors/ loops), including our assessment of the extent to which each country programme has progressed along this chain. This is followed by details for each country.

Figure 4.1: Logic chain of results and country progress



The most significant and tangible results in terms of influencing policy makers have been made in Malaysia, where:

- A high-level commitment has been made by the government to assess the possibility of issuing a CL for sofosbuvir and the rejection of data exclusivity for daclatasvir. Many stakeholders noted that the project partners have played an important role in getting the government to this stage and that without the project, the data exclusivity would have most likely been issued.
- The project has created a "champion" Parliamentarian on accessing affordable HCV medicines, who in turn arranged a Parliamentary roundtable. Six Parliamentarians attended, which the Deputy Minister of Health chaired, showing the high profile interest that had been generated for this issue.

In Morocco and Colombia, whilst results have not been achieved to date, there is significant potential for results in this area.

- In Colombia, the issue of HCV treatment costs is on the government's agenda, in part due to the work of Ifarma. This follows Ifarma advocating for a declaration of public interest for HCV (a first step for the country issuing a CL). While this took place before the Colombia programme commenced, stakeholders noted that the support of this project has allowed Ifarma to continue its advocacy work in this area. Ifarma has also began engaging with universities and research institutes on implementing a pilot programme to produce magistral drugs, which will allow access to treatment for as little as US$300. This was expected to be operational by the end of April 2017.
- In Morocco, project partners played a key role in developing the National Strategic Plan to fight viral hepatitis prior to project start, which has placed them in a strong position to influence the design of the implementation plan. Further, the investment case currently being developed is likely to be strong advocacy tool in terms of encouraging a dedicated budget line.

However, in Thailand there is limited potential for results to be achieved in this area within the project timeframe given the project partner focus empowering communities to advocate, rather than direct advocacy to policy makers.

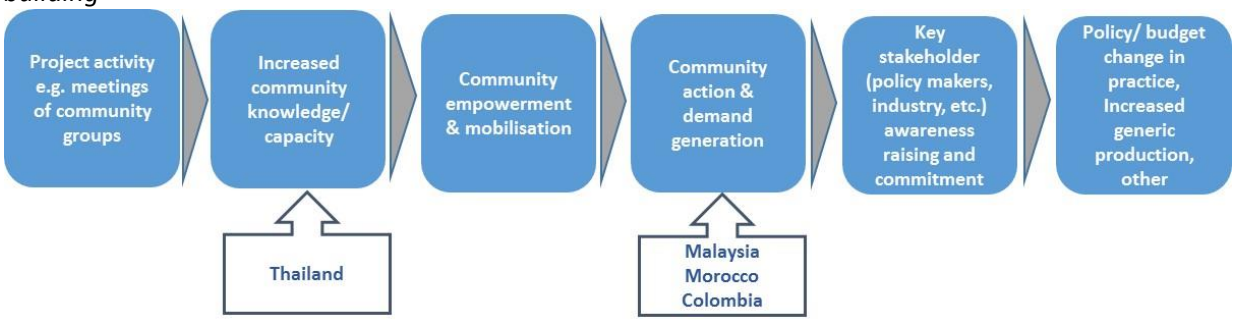
Further, we note that the project approach has predominantly been to work within each project country, with limited provision for cross-country or regional advocacy activities. The project has provided some support in Colombia where, given the difficulties faced issuing a CL for cancer drugs, the country is pursuing a regional approach to issuing a CL for key HCV drugs, agreed with other South American countries as part of the meeting at UNASUR on World AIDS Day in 2016. We note that expanding such an approach may have been beneficial in terms of information sharing and joint working.

Increased knowledge and capacity of civil society for HCV

Figure 4.2 presents an indicative logic chain of results for community engagement/ empowering activities (for simplicity, presented as linear and without reference to external

factors/ loops), including our assessment of the extent to which each country programme has progressed along this chain. This is followed by details by country.

Figure 4.2: Logic chain of results and country progress for civil society awareness and capacity building



Across all county programmes, results have been achieved in terms of increasing civil society knowledge and awareness of HCV treatment, with further potential also evident.

- In Malaysia, the awareness raising work with communities to develop action plans has already started to see some positive results. For example, advocacy to the Muslim Council has led to direct funding to purchase DAAs through buyers' clubs. Furthermore, this activity has empowered community groups to advocate for change, with nine patient groups signing a letter to the MoH regarding pending patents for sofosbuvir and velpatasvir. Additionally, a strong commitment has been made by local generic manufacturers to produce DAAs and activities are already underway to prepare the ground for registration once a CL has been issued.
- In Thailand, while actual results to date are relatively limited, project partners have been active in building awareness of HCV among PWID and given their strong networks and experience in this, there is potential for this to generate wide demand within that target population.
- In Morocco, ALCS has introduced HCV testing and access to treatment in prisons, which is identified as a high-risk group. There are also a set of awareness raising activities planned, including creating a website, developing brochures and broadcasting a radio advert, which have potential to achieve results.
- In Colombia, a significant amount of interest has been generated for improved HCV treatment and information on testing following project partners significant efforts of working with patient organisations and creating new interest groups since receiving support from the project. Patient organisations are now discussing HCV-related issues with the media and local health authorities.

Increased coordination between CSOs and creation of a CSO movement for HCV

Additionally, the project has facilitated coordination amongst different stakeholders. Whilst this has not yet led to tangible results, there is potential for results to be achieved.

Details by country are as follows:

- In Malaysia, the project has been important for bringing the project's CSOs together in a coordinated fashion. Prior to the project, TWN and MAC rarely worked with each other.[21] In addition, the project has expanded the scope of work for MAC to include a focus on HCV.
- In Thailand, Ozone have been trying to get involved in HCV activities for four years and this is the first time funds have been received. This therefore legitimises the voice of Ozone within the HCV space.
- In Morocco, the project has established a CSO platform in March 2017, which has already sent a joint letter to the Government regarding commitment to the National Strategic Plan for viral hepatitis.
- In Colombia, the project has facilitated communication between Ifarma and key regional CSOs, who have been important for spreading awareness of HCV across different parts of the country.

Overall results

Although the project is unlikely to achieve all its intended results by December 2017, given the limited time for implementation and need for longer timeframes given the advocacy-based approach, the work undertaken both by C+ and the country partners in most countries has laid a solid foundation for ensuring that advocacy efforts can contribute to improving access to HCV treatment in the project countries and stakeholders have viewed the approach as being appropriate. However, achieving this will require a longer-term commitment from UNITAID than currently provided under this grant.

4.1.2. Added value of the project

In all countries, stakeholders noted that the project has been important for mobilising in-country advocacy efforts for improved HCV treatment, and without the project efforts activities would have been considerably less organised, more piecemeal and of lower priority. The degree to which the project has represented added value differs by country, with some country partners noting that they were only able to become involved in HCV issues due to project support (e.g. MAC in Malaysia), and others noting they would have managed to do most project activities anyway, although to a lesser degree (e.g. ALCS in Morocco). Specifically, we note the following for each country:

- In Malaysia, TWN would have conducted several of the advocacy activities with policymakers in spite of the project. However, the project has enabled TWN to be far

[21] It should also be noted that MAC and TWN had not previously working together partly due to personal differences between senior staff. However, staff have changed since the start of the project.

more focussed and expand the reach of their voice. Specifically, without the project, it is likely that the data exclusivity would have been approved for daclatasvir and that slower progress would have been made in terms of government commitment to a CL. Further, the project enabled MAC to enter the HCV space for the first time, which is likely to have a lasting impact.

- In Thailand, it is unlikely that either TTAG or Ozone would have been able to implement any of the activities without the project funding.
- In Morocco, ALCS noted being able to do "infinitely less" without the project support. Whilst ALCS would retain a focus on HCV even without project support, this would have to be done using HIV-related budgets and without dedicated staff to lead activities, likely resulting in less structured activities.
- In Colombia, Ifarma noted that they were already working with the government on HCV issues and could have continued, albeit at a slower pace with likely lower impact. However, without the project they would not have been able to implement any of the community awareness raising activities; a new project approach for Ifarma.

Stakeholders also noted that the coordination activities at the global level were useful mechanisms for bringing partners together in a manner that may not have taken place in the absence of this project. Given the significant lack of HCV-funding, many partners noted a key added-value of the project being to prove that results could be achieved through this approach and therefore UNITAID is acting as a potential catalyst for other donors to also enter the HCV space. Indeed, ITPC-MENA is already an example of this, with another donor (Robert Carr Fund) now funding activities previously covered by this UNITAID grant. However, we did not receive any evidence that the project had had any "spill-over" effect in any non-project countries.

Summary findings:

The work undertaken both by C+ and the country partners in most countries (with the exception of Thailand) has laid a solid foundation for ensuring that advocacy efforts can contribute to improving access to HCV treatment in the project countries. However, achieving this will require a longer-term commitment from UNITAID than currently provided under this grant.

4.2. Sustainability

7. Has the project adequately considered sustainability aspects?

Given the project's goal of contributing to universal HCV treatment care in lower and middle income countries, sustainability is a key consideration of the project, both in terms of ensuring the project's results are maintained and to ensure activities can continue in the

absence of project funding. This assumes particular importance given the short two and a half year timeframe of the project and the delayed start of activities in most countries.

While HCV is starting to be recognised as an important issue within the international community, donor funding remains limited, especially when compared to support for other diseases. For example, while the Global Fund has committed to funding HCV as part of its support for addressing HIV co-infections (and has also provided funds in some countries), this is likely to be limited, given its core mandate to fund the three diseases and the range of criteria to be satisfied (e.g. based on a strong investment case and has a disproportionate impact on PLHIV).[22]

This lack of international support explains the rationale for the project focusing on mobilising domestic commitment and funding to improve HCV treatment. However, as noted in Section 4.1.1, this has not been realised in the project countries as yet (not anticipated by 2016 in the logframe), and is unlikely to be realised before the end of this grant (only anticipated for one country by project close). Therefore, advocacy efforts will likely need to be continued beyond the duration of this grant, recognising the time lag between advocacy activities bearing results.

The specific activities of the project also rely considerably on the funding from UNITAID for ensuring activities continue. This is evident from a number of staff both at HQ country CSOs being either wholly or partly funded by this project. Therefore, a lot of the organisations within this project are reliant on the funding from UNITAID for their activities, with little evidence of a transition mechanism being put in place.

Given these issues, we assess there is risk that the progress generated thus far will be diluted without ongoing advocacy work after the conclusion of the grant in December 2017. This is largely due to results not yet being fully achieved, especially in countries where activities are only just getting underway. Lack of ongoing support presents the risk of a wasted investment, especially given the investments already made in getting started.

Summary findings:

With the limited funding landscape for HCV, without ongoing support, results achieved to date face the risk of dilution, potentially rendering investments made so far as largely wasted.

[22] Global Fund (2015), Thirty-third Board Meeting – Global Fund Support for Co-infections and Co-morbidities

5. CONCLUSIONS, LESSONS LEARNED AND RECOMMENDATIONS

This final section presents conclusions and lessons learned from the project to date, and also provides recommendations for the project going forward.

5.1. Conclusions and lessons learned

The UNITAID- C+ HIV-HCV affordability project is much valued and seen as being very relevant by all stakeholders consulted, particularly given the low levels of attention to HCV globally. Access to and affordability of DAAs continues to be a major barrier to treating patients, particularly in the selected project countries.

In terms of implementation, the project has been beset by delays from the very start. The extended time needed by C+ to recruit all dedicated project staff and the extended time for "on-boarding" countries has resulted in overall delayed project implementation, most notably implying a reduction in time to implement country-level activities and achieve country-specific targets.

These initial delays have highlighted that the phased approach employed by the project was appropriate and that the alternative of launching all activities simultaneously was not feasible given C+ initial capacity constraints. Whilst a detailed review of C+ capacity has not been undertaken here given the ongoing operational review, stakeholders, including UNITAID, have noted an improvement in C+ capacity over time, also with an effective HAP in place.

The implementation of most global level activities has been positive, with a well-regarded partner coordination meeting, although there have been some delays, particularly in terms of the investment cases. As regards country activities, programmes are now being rolled out in almost all countries and implementation has been positive in most circumstances, with some notable results already achieved. Key country-level project results to date include:

- Contracting appropriate and influential partners in most countries.
- Facilitating government commitment to HCV issues in Malaysia, where a CL is currently being considered.
- Contributing to increased government awareness of HCV in Colombia, where HCV treatment costs are now on the government's agenda, and in Morocco, where the implementation plan for the National Strategic Plan to fight viral hepatitis is currently being developed.
- Empowering CSOs to act towards policy change/ demand generation, through supporting communities to develop action plans in Malaysia, enabling access to HCV treatment in prisons in Morocco, and generating demand amongst community groups in Colombia.

- Contributing to increased awareness by civil society of HCV issues in Thailand, building on existing networks of PWID.
- Enabling all implementing partners to become more engaged in HCV advocacy issues and effectively coordinate activities, which they would otherwise not have been able to do.

Whilst the project is certainly moving the right direction, achieving the overall goal and outcomes within the project timeframe is unlikely, particularly given the short project time remaining. Even in countries that are closer to achieving key milestones (most notably Malaysia), the project goal of a universal HCV treatment programme is unlikely to be launched before December 2017.

As with all advocacy interventions, achieving the desired results will be determined by a range of confounding and external factors, not least having sustained commitment from government to ensure policies are effectively implemented (which is challenging with frequently changing governments). Notwithstanding this, the multi-pronged approach of the project in terms of targeting policymakers, empowering communities and building knowledge is viewed as enabling results to be achieved over the longer time horizon – and indeed early results are already being observed. Therefore, while there is a risk that project results will not be achieved given the upstream nature of interventions, evidence from the project to date suggests that **not continuing activities beyond December 2017 will dilute the momentum achieved to date and retard progress and opportunities for policy change and community empowerment**. An additional and significant risk is with regards to the sustainability of project-specific results, given the reliance project partners have on UNITAID funding, combined with the current absence of alternative funding sources/ interest. As such, we assess that continued UNITAID funding in this area is critical to ensure continued momentum and progress in this area.

Further interventions will be required to achieve results, the exact nature of which will vary by country, both in terms of length of support and the appropriate approach. For example should Malaysia issue a CL, support would then be required in terms of health systems enabling. Given that outcomes are affected by a range of external factors, the focus of any continuation of support would need to be continually monitored to ensure relevance. It would also be important to ensure focus of activities are continually aligned with UNITAID's mandate for impacting market dynamics and improving commodity access, rather than broader advocacy objectives. However, this evaluation is unable to say with any certainty that a project extension would lead to intended results, recognising the high risk-high innovation nature of all UNITAID grants.

Lessons learned at this stage of project implementation include:

- **Establishing realistic timelines:** Activities have suffered from delays, which have largely been linked to C+ initial capacity constraints. However, it would have been more appropriate to set realistic timelines that took into account these constraints.

This was particularly the case for Phase 1(a), where for example the process to contract project partners in Thailand was conducted before C+ was operating at full capacity and created a missed opportunity in inability to bring on board the most relevant CSOs. Realistic timelines are also needed to reflect the nature of advocacy interventions that have a time lag for results.

- **Increasing the flexibility of country management**: The nature of advocacy-based interventions means that changing contexts often require a refocusing of activities, and a consequent need for a flexible approach to project management. However, C+ processes for managing country partners have not always enabled such flexibility. Whilst low country partner capacity is one reason for this, in order to not negatively impact on potential project achievements or timely implementation, it will be important for C+ to provide greater flexibility, especially when changes do not have an impact on the overall project budget.
- **Improving project monitoring and reporting, including risk management:** The project M&E framework is not robust enough to adequately capture project progress, with inadequate measurement of country-level activities, lack of clarity in targets and limited measurement of outcomes. The project risk assessment approach was weak, focusing on risks outside of project control and not identifying a number of key risks. In addition, while some risks have been identified at the country level, guidance on how to mitigate against these risks could be improved.

5.2. Recommendations

Based on the evaluation conclusions and lessons learned, we provide the following recommendations. Annex E presents further country-specific recommendations.

Recommendation 1: Consider extending the project, should progress continue in a similar manner and country contexts remain unchanged

Given the significant investments made for this project, both financial and in terms of capacity building and establishing networks, it would represent a missed opportunity for this project not to bear sustainable results. To date, the project has laid a solid foundation for the *potential* achievement of results, but these are only likely to be realised over a longer period. In addition, a significant proportion of project funds (23%) are expected to be unspent at the end of the project. UNITAID and C+ should therefore critically consider, on a country by country basis, the most effective approach and realistic timeframes to enable project goals to be achieved. This assessment should take into consideration project progress to date, remaining country needs, and planned actions by other actors, any changes in country context and a comprehensive risk assessment, amongst other issues.

We highlight that our recommendation is from the programmatic and country impact perspective, and UNITAID should also consider the findings of the operational review whilst deliberating project extension.

Recommendation 2: Re-evaluate the project approach in Thailand to ensure that project results can be achieved

Country partners in Thailand are relevant for the community mobilisation project aspects. However, a close review of planned activities is required to ensure they will lead to expected results. For example, whether there are sufficient activities to effectively establish PLHCV groups and whether proposed policy-level advocacy activities can bring about change in the project lifetime.

Further, the current approach will not be sufficient to achieve overall project goals. Whilst other Thai organisations have been providing limited support to the project and there are currently initial discussions to include another partner in Thailand with expertise in advocating to policy makers, which is expected to provide the project with the multi-pronged approach that appears to be working well in other countries.

We provide a strong recommendation that without revisions to the Thailand programme, a continued use of UNITAID resources represent ineffective use.

Recommendation 3: Refine the overall monitoring and reporting approach of the project

The current M&E framework fails to adequately capture how project activities are contributing to overall project results, and therefore refinements should be considered as suggested below.

As a starting point, **the M&E framework should be based on a 'theory of change' that considers how project activities, outputs, intermediate outcomes, outcomes and impacts are interrelated**, as well as identifying milestones, relevant to UNITAID's mandate and which notify the point at which UNITAID's catalytic role has been achieved. This will ensure that all project activities are accurately captured in project monitoring, as well as outlining the logical progression from outputs, to intermediate outcomes and then to outcomes. It is likely that modified frameworks will be required for each implementing country given variations in approach and differing country contexts.

Second, there is a need to **re-define or include additional measurements so that intermediate outcomes are more effectively captured**. This is particularly important for an advocacy-based project, given the expected time lag (and thereby the importance of measuring "incremental changes") and multiple confounding factors involved in achieving project outcomes and impact. For example, while the number of meetings with policymakers is a relevant *activity* to be pursued and a relevant *process indicator* to measure, the *intermediate outcome* of this activity is the extent to which it increases awareness and interest. Therefore a better means of measuring this could be by, for

example, consulting with independent stakeholders in-country or conducting feedback surveys following project events. This implies the use of more varied M&E approaches than a quantitative logframe alone (although survey feedback could feed into a logframe results). We view the use of multiple M&E approaches as very relevant for advocacy interventions in particular (where the results are not always quantifiable as is the case with commodity funding), although note that the extent of use needs to be balanced with associated costs.

Third, **individual country logframes should be retained, with a more qualitative representation of overall progress provided by country**. For example identifying each country progress along the theory of change, similar to how progress has been captured in Figure 4.1 and Figure 4.2 (Section 4.1.1), or adopting a traffic light approach for the extent to which each country is on track to achieving results, similar to that presented in Tables 3.2, 3.3 and 3.4 (Section 3.3.2). **Quantitative measures that feed into UNITAID's logframe monitoring should only be done on a project-wide basis**, using indicators that effectively capture overall progress.

Finally, and related to the previous suggestion, **greater focus should be placed on qualitative reporting of activities and outcomes**. To date, country updates have focused heavily on whether activities have been implemented, with limited details provided on *how* these activities have resulted in any change and some key results have not been reported at all (for example, how the project has improved CSO coordination). Going forward, a **more structured progress report template should be developed**, reporting against the theory of change, to present the rationale on the choice of activities/ relevance of stakeholders targeted and include narrative on how activities have led to any change, as well as how external factors have positively/ negatively affected project achievements.

Recommendation 4: Develop a more robust risk management framework

While we note that the risk management approach has improved overtime, further work is needed to identify and manage key risks going forward. This is particularly important given the high risk nature of an advocacy project, which is largely upstream in nature and exposed to a wide range of external factors. **Such a risk management framework should put greater emphasis on immediate risks within the project's control**, as opposed to focusing on external risks. Further, at the macro level, the limited range of actors/ donors in the HCV space presents a key risk, for which mitigating actions are required to enable some degree of sustainability.

At the country level, further support should be provided by C+ to help country partners address relevant risks within the project. This risk management framework should clearly outline how these risks will be managed and provide guidance to country partners on how they might address risks that have been identified.

Recommendation 5: Clearly define country project management arrangements to allow for greater country flexibility, whilst retaining accountability

There is **a need for C+ to redefine its approach to management of country partners**. Country partners should be given increasing flexibility for making minor programmatic and budget amendments, particularly if there is no material change in the overall country budget, noting this needs to reflect the different capacity levels amongst partners. This may include increasing decision making autonomy to country partners, outlined as part of a set of rules and procedures. Whilst a review of the manual of procedures developed by C+ is outside the scope of this review, emerging findings from the operational review should be actioned in light of this recommended change.

It may also be appropriate for UNITAID to further communicate in writing to C+ its contractual obligations, particularly regarding requirements around managing country budgets, to avoid future communication issues and avoid potential delays to project activities.

Recommendation 6: Ensure all project activities maximise their strategic impact

Now that many country level activities are well under way, there is a need for C+ to provide support to country partners in strategically reviewing the extent to which each activity will reach the intended impact, as well as to ensure that each activity/ targeted stakeholder is the most relevant. For example, the project is developing a body of evidence on HCV issues and it will be critical that activities are included to maximise the impact of this information, such as through a targeted dissemination strategy or a plan for policy change. This is also closely linked to our recommendation 1 above on project extension, where these aspects need to be carefully considered.

Recommendation 7: Improve project links across countries and with project global activities

Whilst there are a number of coordination mechanisms in place for this project, including global meetings between partners, there may be further scope for partners to work together on a more operational level in order to draw lessons from different country programmes, and create more formal links between country programmes, as well as between global and country level activities. For example, to learn lessons from Colombia's ability to raise awareness among key populations. Project countries could also establish a mentoring relationship with non-project countries, including increased engagement with the HAP.

Recommendation 8: Leverage opportunity to raise HCV profile through project coordination with other global events/ associations

Project countries should play an active role in jointly raising awareness on HCV issues, with the aim to build the global HCV momentum for demand creation. This could be achieved

through jointly marking World Hepatitis Day and presenting project achievements or hosting special sessions at relevant conferences and events to capitalise on engaging relevant participants. Relevant events include the second World Hepatitis Summit to be held in Brazil in November 2017 and regional liver conferences, such as those organised by the American Association for the Study of Liver Diseases (AASLD), the Asian Pacific Association for the Study of the Liver (APASL) and the European Association for the Study of the Liver (EASL).

ANNEX A LIST OF REFERENCES

Annual and semi-annual reports

C+ (2015), 2015 Annual Report

C+ (2016), 2016 Semi-Annual Report

C+ (2017), 2016 Annual Report

MAC (2017), 2016 Annual Report (Malaysia)

MTAAG+ (2017), 2016 Annual Report (Malaysia)

TWN (2017), 2016 Annual Report (Malaysia)

TTAG (2017), 2016 Annual Report (Thailand)

Country reports

C+ (2016), Country Report – Colombia

C+ (2016), Country Report – Malaysia

C+ (2016), Country Report – Morocco

C+ (2016), Country Report – Thailand

CSO outputs

TWN (2016), HCV Brief 1 – Access to Hepatitis C medicines

TWN (2016), HCV Brief 2 – Compulsory Licensing/Government Use Licenses

TWN (2016), HCV Brief 3 – Thailand's Compulsory Licenses Experience

TWN (2016), HCV Brief 4 – Patents and high DAA prices in Malaysia

Disbursement memorandums

UNITAID (2015), First Disbursement Memorandum

UNITAID (2016), Second Disbursement Memorandum

UNITAID (2016), Third Disbursement Memorandum

UNITAID (2016), Third Disbursement Memorandum

Grant agreements and proposal documents

C+ (2013), HIV/HCV Drug Affordability Project Proposal

UNITAID (2014), HIV/HCV Drug Affordability Project – Proposal Review Committee Assessment Report

UNITAID (2015) Grant Agreement for Phase 1(a) (including Project Plan)

UNITAID (2016) Grant Agreement for Phase 1(b) (including Project Plan)

HAP reports

C+ (2016), HAP Meeting February 2016

C+ (2016), HAP Meeting October 2016

Memorandums for programmatic changes

UNITAID (2016), Additional Country Partnership Manager Memorandum

UNITAID (2016), Investment Case Memorandum

UNITAID (2017), Programmatic Changes to HIV/HCV Drug Affordability Project

Risk assessment & monitoring reports

C+ (2017), Logframe update 2017

C+ (2017), Risk Assessment and Management Update

UNITAID documents

UNITAID strategy and approaches

UNITAID (2011), UNITAID Constitution

UNITAID (2013), UNITAID 2013-16 Strategy

UNITAID (2014) Board Resolution for the HIV-HCV Drug Affordability Project

UNITAID (2015), Hepatitis C Medicines – Technology and Market Landscape Update

UNITAID (2016), HIV/HCV Co-Infection Strategic Narrative

UNITAID (2016), UNITAID 2017-21 Strategy

UNITAID (2016), UNITAID's Approach to Intellectual Property

UNITAID (2017), HCV Portfolio Update

Wider/External documentation

BMS (2015), HCV Developing World Strategy

DNDi (2016), An Alternative Research and Development Strategy to Deliver Affordable Treatments for Hepatitis C Patients

Gilead (2015), Chronic Hepatitis C Treatment Expansion – Generic Manufacturing for Developing Countries

Global Fund (2014), Thirty-second Board Meeting – Global Fund and Hepatitis C Treatment

Global Fund (2015), Thirty-third Board Meeting – Global Fund Support for Co-infections and Co-morbidities

Ministère de la Santé, Royaume du Maroc (2016), Plan Stratégique National de Lutte contre les Hépatites Virales (*National Strategic Plan for viral Hepatitis)*, 2017-2021 (draft)

WHO (2016), Hepatitis C Fact Sheet

WTO (2015), WTO members agree to extend drug patent exemption for poorest members

ANNEX B INCEPTION PHASE CONSULTATIONS AND INTERVIEW GUIDE

This annex lists the UNITAID Secretariat staff we have consulted with during the inception phase of the project and the interview guide used for these consultations.

B.1. List of consultees

Table B.1 lists UNITAID staff members consulted during our inception phase visit to Geneva.

Table B.1: UNITAID Secretariat staff consulted

Staff member	Position
Philippe Duneton	Deputy Executive Director
Robert Matiru	Operations Director
Kate Hencher	Programme Manager
Romane Theoleyre	Programme Officer
Karin Timmermans	Strategy Manager/IP Technical Manager
Gauri Khanna	M&E Officer
Jemmy Dopas	Grant Finance Officer
Nargiza Mazhidova	Data Analyst

B.2. Inception phase interview guide

Project context

1. Please describe the origins of the project in terms of the initial discussions between UNITAID and C+ and how the grant was shaped to its current design? What were priorities emphasised by UNITAID and what were key points from the Proposal Revie Committee (PRC) review and Board approval of this grant?

Relevance

2. How does the project fit and align with UNITAID's mission and both the 2013-16 and 2017-21 strategies? Has the significance of the project changed with the new strategy? How does the nature of the activities supported align with UNITAID's mandate?
3. How do the project goals align with the global response to HCV treatment and the work of other actors?

Implementation effectiveness and efficiency

4. Has the design of the project in terms of focus activities, structuring of phases, etc. worked well? What is emerging learning on aspects that need to be revised/ improved?
5. Has Phase 1(a) helped lay a good foundation for Phase 1(b)? What could have been done better in the initial phase and what remain as key issues for the current phase?

6. How has C+ performed with regards to the implementation of this grant? Are there any aspects of the project's success or failures directly attributable to C+'s operations?
7. Has the project progressed as planned in terms of timeliness and budget spend? If not, what have been key issues?
8. Has C+'s approach to country and CSO selection worked well? Has C+ worked effectively with CSOs/ HCV platforms in country? Have the various advocacy activities been effectively designed and implemented?
9. Is the project on course to achieve planned outputs and objectives? What are the main factors supporting or impeding project progress? Have adequate risk mitigation approaches been incorporated in the project design?

Impact and learning

10. Has the project logframe been well set up and has programmatic and financial reporting worked well to date?
11. What is the potential impact and value for money of UNITAID's investment in the project? To what extent have policymakers across focus countries expressed their support for improving HCV treatment and what remain as key challenges? What difference is the project making?
12. What are the key learnings from the project to date and is there a need for any course-correction or risk mitigation?

ANNEX C CORE PHASE CONSULTATIONS AND INTERVIEW GUIDES

This annex provides the list of consultees interviewed and the corresponding interview guides.

Consultee lists

Table C.1: Global consultee list

Organisation	Name	Position
C+	Khalil Elouardighi	Advocacy Director
	Maria Donatelli	Hepatitis Advocacy Manager (Project Manager)
	Kolia Benié	Country Partnership Manager
	Jean Luc El Kaim	Country Partnership Manager
	Hélène Boscardin	Country Partnership Manager
	Chase Perfect	ATM Policy Officer
HAP members	Ellen 't Hoen	Consultant/Researcher (Medicine Law and Policy), University of Groningen
	Charles Gore	President, World Hepatitis Alliance
	Rosmawati MoHamed	Hepatology Researcher and Professor, University of Malaya
	German Velasquez	Special Adviser on Health and Development, The South Center
	Isabelle Andrieux-Meyer	Medical doctor (MSF and DNDi HCV work)
MSF	Stephan Grosserueschkamp	UNITAID Grant and Pool Manager
DNDI	Graciela Diap	Medical Coordinator
WHO	Philippa Easterbrook	Hepatitis Programme
FIND	Francesco Marinucci	UNITAID Grant Manager
CHAI	Taryn Barker	Director, Hepatitis Program
MPP	Esteban Burrone	Head of Policy

Table C.2: Country visit consultee list

Stakeholder group	Organisation	Name	Position
Colombia			
Project CSO	Ifarma	Francisco Rossi	Director/ Project Manager
		Luz Marina Umbacia Bernal	Advocacy officer
CSO	Mision Salud	Andrea Carolina Reyes Rojas	Deputy Director
Government	MoH	Maria Juliana Rodriguez Gomez	Minister advisor
Malaysia			
Project CSOs	Third World Network (TWN)	Yoke Ling Chee	Director of Programmes
		Karina Yong	Research and advocacy officer
	Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)	Edward Low	Coordinator
		MoHd Al Khusyairi	Communication and Mobilization Officer
	Malaysian Aids Council (MAC)	Parimelazhagan Ellan	Director
		Shangeetha Thirumayni	Campaign Officer
CSO	My commitment to Cure – Hepatitis C	Pr Rosmawati MoHammed	Chairman
NGO	DNDi	Jean-Michel Piedagnel	Head of South-East Asia Office
Trade Organisation	Malaysian Organisation of Pharmaceutical Industris (MOPI)	Peter Rayar	Vice-President
Generic pharmaceutical manufacturer	UNIMED	Dr MoHd Aswad Ramil	Business Development Manager
		Yeap Yoke Bing	Pharmacist
Policy-Maker	Parliament of Malaysia	Charles Santiago	Member of Parliament
Morocco			
Project CSO	ALCS	Hakima Himmich	President

Stakeholder group	Organisation	Name	Position
		Fouzia Bennani	Director
		My Ahmed Douraidi	Advocacy director
		Khaoula Hajaraby	Project officer
CSO	ITPC-MENA	Othoman Mellouk	President
	Collectif marocain droits à la santé (CMDS)	Dr Aziz Ghali	Coordinator of CMDS
Public health agency	Institut Pasteur	Pr Naima El Mdaghri	Director
Government	DGAPR	Dr Regragui	Manager, Health Department
Government/CSO	Parliament/ Coalition Marocaine pour le Droit à la Santé	Dr Chenaoui	Parliamentarian/ Member CMDS
IGO	WHO	Yves Souteryand	Country Director
Pharma	Pharma 5	Myriam L. Filali	CEO
Consultants	Pharos Health	Robert Hecht	President
	Pharos Health	Abderrahman Benmamoun	Associate
Thailand			
Project CSOs	TTAG	Paisan Suwannawong	Director
		Jirasak Sriparmong	Project Manager
		Washarasak Wichitchan	Advocacy Officer
		Pascal Tanguay	Consultant
	Ozone	Piyabutr Nakapiew	Director
		Jindarha Ittimayteeamorn	Project Officer
CSO	AIDS Access Foundation (AAF)	Chalermsak Kittitrakul (Jockey)	Director
CSO	TREAT Asia	Giten Khwairakpam	Project Manager
NGO	Dreamlopments	Dr. Nicolas Durier	Founder and Director
IGO	Global Fund	Philippe Creac'H	Fund Portfolio Manager (Thailand)
IGO	UNAIDS	Tony Lisle Tatiana Shoumilina Dr. Maria Borromeo	Regional Programme Adviser – Community Mobilisation & Network (Asia and the Pacific)

Stakeholder group	Organisation	Name	Position
			UNAIDS Country Director – Thailand Regional Investment and Efficiency Adviser – Regional Support Team (Asia & the Pacific)
IGO	WHO	Dr Mukta Sharma	Programme Manager – HIV/TB/Hepatitis

Interview guides

C.1. Interview guide: C+

1. Please provide the context to the project in terms of C+'s initial proposal to UNITAID and the discussions that led to the approval of the final Phase 1 project?
2. What have been key changes to the HCV treatments market since project inception? Does the project remain relevant given these changes?
3. How do the project goals align with the global response to HCV treatment and the work of other actors? How have the envisaged project activities on the "Coordination Space" progressed?
4. What aspects of the project design have worked well and less well (e.g. focus and range of activities (including mix of global-country activities), phased/ waves approach, country selection, project partner roles and responsibilities, monitoring approach, other aspects)?
5. What was the experience with implementation of Phase 1(a) activities? What worked well and less well and has this work helped lay a good foundation for the next phase?
6. What has been the experience with implementation of Phase 1(b) to date? Please describe successes and challenges with: (i) completion of HQ staffing plans; (ii) in-country activities (scoping, CSO selection, work planning, ongoing management); and (iii) global activities including the HAP, market intelligence reports, coordination mechanisms, etc.
7. Have sufficient resources been provided for both HQ-related activities and in-country activities? Have timelines been realistic? How has the project performance with respect to planned versus actual expenditures and timelines? What are the key reasons for deviations, could they have been circumvented and what measures are in place to address any implications thereof?
8. What is your assessment of C+'s capacity to deliver the project? What measures have been put in place to support effective delivery and what remain as key issues?

9. How has C+'s engagement with UNITAID worked during the project? What have been key challenges and how have these been overcome?
10. What are the key risks facing the project and how have these been planned for/ addressed?
11. How were the country partners identified and selected? How effective have they been at implementing country programmes to date? How has the experience varied by country?
12. Have the most effective activities have been selected and prioritised? How have CSO's approached the various work plan activities to ensure impact? What are emerging country perceptions on the utility of the advocacy work? What have been supporting and impeding factors at the country level? How has the experience varied by country?
13. Will the project outputs and outcomes be achieved by the anticipated timeline? What are the main factors supporting or impeding project progress?
14. What change or difference will the project activities bring about? What might have happened anyway in the absence of the project?
15. To what extent are project activities and intended results likely to be sustained after the project is completed? How important is the project funding for country partners and do they have access to alternative sources of funding for continuation of their work? What factors would determine sustainability of intended project results?

C.2. Interview guide – other HCV actors

Project background and summary included as part of the interview guide.

1. To what extent was advocacy support to improve HCV drug affordability needed in the selected countries? Does the project still remain relevant given changes in the HCV treatment market since its inception?
2. How do the project goals align with the global response to HCV treatment and the work of other actors? Are there areas of the project's work that you feel compliments and/or duplicates the work of others?
3. What experience do you have of working with C+ and the in-country partners? Do you think that these partners were the most appropriate for delivering the projects activities? How does their work complement the work of other actors?
4. Are the focus activities under this grant the most appropriate for achieving the project's goals and objectives? Do you believe that certain activities should have been prioritised over others, given the country contexts?
5. What progress has been made with regards to improving government commitment to ensuring affordable access to HCV treatment? What results are likely to have been achieved in the absence of the projects activities?

C.3. Interview guide – HAP members

1. To what extent was advocacy support to improve HCV drug affordability needed in the selected countries? Does the project remain relevant given changes in the HCV treatment market since its inception?
2. How do the project goals align with the global response to HCV treatment and the work of other actors? Are there areas of the project's work that you feel compliments and/or duplicates the work of others?
3. What was the experience with implementation of Phase 1(a) activities? What worked well and less well and has this work helped lay a good foundation for the next phase?
4. What aspects of the project design have worked well and less well (e.g. focus and range of activities (including mix of global-country activities), phased/ waves approach, country selection, project partner roles and responsibilities, monitoring approach, other aspects)?
5. What has been the experience with implementation of Phase 1(b) to date? What has worked well and less well with: (i) in-country activities (scoping, CSO selection, work planning and prioritisation, CSO implementation, ongoing management by C+); and (ii) global activities including the HAP, market intelligence reports, coordination mechanisms, etc.
6. Have sufficient resources been provided for both HQ-related activities and in-country activities? Have timelines been realistic?
7. How has C+ performed with regards to project management? How has C+'s engagement with UNITAID worked during the project? What have been key challenges and how have these been overcome?
8. Will the project outputs and outcomes be achieved by the anticipated timeline? What are the main factors supporting or impeding project progress?

C.4. Interview guide – country stakeholders

Project CSOs	Policymakers/ government	Other CSOs/ observers
1. What are the key challenges impeding HCV treatment in your country? What are key opportunities for enhancing HCV treatment? 2. What is the need for advocacy support for improving HCV drug affordability in your country? 3. Please describe the	1. What are the key challenges impeding HCV treatment in your country? What are key opportunities for enhancing HCV treatment? 2. How has the project CSO engaged with you with regards to increasing access to HCV treatments? What activities have you been involved in?	1. What are the key challenges impeding HCV treatment in your country? What are key opportunities for enhancing HCV treatment? 2. To what extent was advocacy support to improve HCV drug affordability needed in the country, given other developments and activities that were taking place at the time? 3. Do you believe the most appropriate in-country partner was selected to

Project CSOs	Policymakers/ government	Other CSOs/ observers
selection process for your appointment under the project – what worked well and less well? 4. How were activities identified and selected? Do you believe these have been the most appropriate activities to pursue? Were any activities not included that you believe would have been useful? 5. Are the resources and timeframes adequate for country activities and intended results? 6. Please describe each of the advocacy activities funded by the project in terms of their scope, implementation to date, implementation experience and benefits achieved? 7. What progress has been made with regards to improving government commitment to ensuring affordable access to HCV treatment? What are the main factors supporting or impeding project progress? To what extent can this be attributed to the activities of the project? 8. What progress has been made with regards to mobilising communities and the general population for improved HCV treatments? What are the main factors supporting or impeding project progress? To what extent can this be attributed to the activities of the project? 9. What results are likely to have been achieved in the absence of the projects activities? 10. To what extent are results likely to be sustainable after the project is completed?	3. Do you view these activities to have been well planned for and managed? What was the benefit of the activity/ engagement? What could have been done better? 4. What more could be done to encourage policy commitment towards increased and improved HCV treatment? 5. Is the project CSO well informed of key issues impacting HCV treatment in your country? 6. Do you believe the most appropriate in-country partner was selected to implement the project? 7. What difference do you think the project activities will make with regards to government policy and commitment (including budget allocation) for HCV treatment?	implement the project? Are there other organisations that are also working in the advocacy space that have significant influence in government? 4. Do you believe the most appropriate activities are being pursued through the project? Were any activities not included that you believe would have been useful? 5. To the extent you are aware, what has been the experience with implementation of the activities? What considerations have gone into their implementation? What would be the benefits? 6. What progress has been made with regards to mobilising communities and improving government commitment to ensuring affordable access to HCV treatment? What are the main factors supporting or impeding project progress? To what extent can this be attributed to the activities of the project? 7. What results are likely to have been achieved in the absence of the projects activities? 8. How do the project activities/ goals align with the work of other actors? Are there areas of the project's work that you feel compliments and/or duplicates the work of others?

Project CSOs	Policymakers/ government	Other CSOs/ observers
11. To what extent does the project coordinate/ compliment/ duplicate the work of others? 12. Are you aware of the planned studies/ reports to be commissioned as part of the project and to what extent are these useful for your country work? 13. How effective have C+ been as a global partner for the project? Do you believe they have managed the country grant efficiently and effectively? 14. Is the balance appropriate between level of resources and management requirements from C+? 15. What are the key milestones/ achievements agreed for the project with C+? How are these being tracked? 16. Are country work plans and activities are being adapted to changing country/ global needs?		

ANNEX D REVIEW OF PROJECT TIMELINESS

Table D.1 lists the start date of selected project activities, and where relevant, provides details regarding why activities were delayed. We highlight in **bold** project delays viewed as significant and impacting overall project delivery.

Table D.1: Assessment of project timeliness

Activity area	Planned start date *(Source)*	Actual start date *(Source)*	Difference	Cause of delay
Global level and wider project activities				
First HAP meeting	December 2016 (*C+ Annual Report 2016)*	February 2016 (*C+ Annual Report 2016)*	2 months delay	Late recruitment of project staff.
Launch of Phase 1(b)	**March 2016 *(Phase 1(a) GANTT Chart)***	**May 2016 *(C+ Annual Report 2016)***	**2 months delay**	**Delays in Phase 1(a) caused by slower recruitment and key documentation not being completed on time.**
International activist meeting[23]	July 2016 *(Phase 1(b) GANTT Chart)*	July 2016 *(C+ Annual Report 2016)*	On time	Not applicable.
Investment cases[24]	**May 2016 *(Phase 1(b) GANTT Chart)***	**February 2017 *(C+ Annual Report 2016)***	**9 months delay**	**Less focus given in the project's initial stages relative to other activities. The scope of the investment cases was also changed.**
Country programmes				
Malaysia	March 2016 *(Phase 1(a) GANTT Chart)*	July 2016 *(C+ Annual Report 2016)*	4 months delay	Difficulties finalising country package given this was the first one, in addition to more time being dedicated by C+ to finalising wider project

[23] Note that we have taken the start date outlined in the Phase 1(b) Project Plan, as Phase 1(a) documentation noted that this would take place in Phase 1(b). Therefore, we see Phase 1(b) documentation as more appropriate for determining the figures for this.
[24] The expected start date is taken as the start date of the "HCV investment & financing case: international" in the Phase 1(b) Project Plan.

Activity area		Planned start date *(Source)*	Actual start date *(Source)*	Difference	Cause of delay
					documentation.
Thailand	**Contract signing**	**February 2016** ***(C+ Annual Report 2016)***	**August 2016** ***(C+ Annual Report 2016)***	**6 months delay**	**Need to restructure project after change in potential partners identified.**
	Activity implementation	**March 2016** ***(Phase 1(a) GANTT Chart)***	**December 2016** ***(Stakeholder consultations)***	**9 months delay**	**Need to restructure project. The launching of activities was further delayed from September to December due to country partners not receiving funds following a mistake made by the Thai bank.**
Morocco		August 2016 *(C+ Annual Report 2016)*	September 2016 *(C+ Annual Report 2016)*	1 month delay	Slight delay as a result of staff availability in-country.
Colombia		November 2016 *(C+ Annual Report 2016)*	October 2016 *(C+ Annual Report 2016)*	1 month ahead of schedule	
Indonesia		**October 2016** ***(Phase 1(b) Project Plan)***	**January 2017** ***(C+ Annual Report 2016)***	**3 month delay**	**Initial planning took place for Argentina but this was subsequently removed and replaced by Indonesia.**
India		May 2017 *(Phase 1(b) Project Plan)*	April 2017 *(Stakeholder consultations)*	1 month ahead of schedule	

Source: C+ (2016; 2017). CEPA analysis.

ANNEX E COUNTRY CASE STUDIES – MALAYSIA, THAILAND, MOROCCO AND COLOMBIA

This annex presents more detailed findings and analysis from each of the four case study countries: Malaysia (Section E.1), Thailand (Section E.2), Morocco (Section E.3) and, to a lesser extent given no in-country visit, Colombia (Section E.4).

E.1. Malaysia

E.1.1. Background

Country burden and key issues

Estimates of the HCV burden in Malaysia suggest around 500,000 people are currently infected, representing a disease burden in the general population of 2.5-3.5%. However, only around 2,000 patients are diagnosed with HCV annually and around 500 people are treated. The main reasons for this include:

- general lack of awareness of HCV in the population;
- limited diagnostics, due to few hepatologists/ gastroenterologists and diagnosis facilities;
- HCV not being a priority public health issue relative to other issues (such as HIV and cancer); and
- lack of a national hepatitis treatment programme, partly due to low government awareness and lack of affordable, effective treatment.

Malaysia generally benefits from a good health system. However, Malaysia's economy has suffered from the recent slump in global oil prices, leading to significant government budget cuts. Corruption in government has also been noted as a wider issue affecting Malaysia's health system, particularly with respect to procuring medicines.

In 2013, the government committed funding for treating HCV, through pegylated interferon/ribavirin. A costed national development plan for HCV is reported as being under development. In addition, the government has contributed US$1m to the DNDi clinical trial of sofosbuvir/ravidasvir. Several stakeholders noted that at present, there is a general government commitment to improve access to HCV treatment, provided that some of the key barriers mentioned above can be addressed, with price of effective treatment generally being regarded as a key impediment to treatment.

DAA licensing situation

Gilead currently has a patent granted for both the sofosbuvir compound and pro-drug in Malaysia due for expiry in 2024 and 2028 respectively, while data exclusivity has been granted until 2018. As a result, Gilead currently has a monopoly in the market, and with the best price of sofosbuvir costing US$30,000 for full treatment, there is only limited availability of DAAs through the private sector. Recently, the government rejected Gilead's

final offer of US$12,000 for sofosbuvir/ledipasvir and sofosbuvir/velpatisvir. Recently, BMS' application for daclatasvir data exclusivity was rejected, thereby removing the main barrier, although registration will still be required.

Given these pricing issues, advocacy efforts to date have focused on getting the government to issue a CL for sofosbuvir. This would allow generic suppliers to provide the drug for government use, thus paving the way for a wider HCV treatment programme.

E.1.2. Project start-up

C+ undertook initial country visits to Malaysia in October 2015 and December 2015. In February 2016, partnerships were formalised and the project workplan was finalised. However, the final contract was only signed in July 2016, which was four months' later than planned. The initial delay was due to the extended time granted to C+ to finalise the budget proposal and templates for the country package. As Malaysia was the first country where activities were being implemented and lessons were still being learned, C+ and other stakeholders noted that this resulted in the project start-up taking longer than Wave 2 countries.

Project partner choice

C+ selected the following three project partners:

- **TWN,** the lead project partner, advocate to policymakers and implementers on access to medicines, intellectual property (IP) rights and trade-related issues. TWN has strong experience in this area, having been involved in advocating for the CL issued in 2003 for HIV, as well as having helped to write the decree on the implementation of data exclusivity for all drugs in Malaysia.
- **MTAAG+** is a network of PLHIV in Malaysia that works closely with communities to build capacity and empower communities to advocate for improved treatment access, amongst other human rights issues. MTAAG+ has been involved in advocating for improved HCV treatment for over four years and their project director is well connected with a number of key HCV advocates.
- **MAC** is an umbrella organisation set up by the MoH to coordinate efforts of several organisations working on HIV/AIDS issues. MAC holds a privileged position in the country, given its close contact to key policymakers in government, and the MoH in particular.

Given this combination of skills and expertise, the project partners are highly relevant, particularly given their complementary skill sets which allows a "multi-pronged" advocacy approach. Stakeholders also noted TWN's role being particularly important for advocating to key policymakers.

E.1.3. Project relevance and design

Stakeholders in Malaysia agreed that the project is relevant to the country context, noting in particular that most HIV deaths are due to HCV co-infection. Given the high cost and lack of access to DAAs, whilst there is some degree of government commitment to address these issues, advocacy-related work is required to ensure this is a priority issue, particularly given the considerable resistance expected from pharmaceutical companies over issuing a CL. However, some stakeholders noted that the project put too much emphasis on PWID, with a need to also include other stakeholders to effectively build momentum, including doctors and medical associations.

Project design

Table E.1 summarises the areas of responsibility and activities of each partner, which were jointly agreed between partners and C+ during the project design phase.

Table E.1: Malaysia country partners and activities

Partner	Area of responsibility	Activities
TWN	• Drug prices and affordability	1. Organise inter-ministry dialogue on HCV DAA access and treatment for 50 participants. 2. Organise expert meetings on medicines pricing for 20 participants. 3. Write and edit four briefing papers for advocacy targeting policy makers, parliamentarians and generic manufacturers.
MAC	• Awareness raising • Diagnosis • Community capacity building (support) • Dialogue with parliamentarians	4. Production of bilingual HCV report (English/Malay), including epidemiological data on HCV situation. 5. Organise parliamentary roundtable on IP.
MTAAG+	• Community capacity building (lead) • Involving marginalised communities in national campaign	6. Plan and implement six community action plans generated at district level after IP & Access to Medicines training for communities in 2015. 7. Develop and deliver training session on HCV to be closer to communities, and then, produce materials and disseminate up to 500 copies.

In addition to the above activities, MAC will also be launching a film festival as part of the project, which will focus on HCV and will be implementing awareness campaigns in universities to raise students' awareness of HCV.

E.1.4. Project implementation

Project progress

According to C+'s 2016 Annual Report, five of the seven planned activities have been completed, with stakeholder agreement that these have largely worked well, including:

- TWN holding a number of bilateral meetings with key government departments that have been influential in highlighting relevant access to medicines issues.
- The mini-roundtable was important for raising awareness with Parliamentarians who previously had little knowledge of the issues associated with HCV.
- Community-based activities have helped to raise awareness of HCV among PWID.
- Groups of PLHCV have more information associated with accessing DAAs and current barriers.

The following activities have been delayed/ amended:

- An experts meeting on medicines pricing was not completed following initial project delays limiting the amount of time to sufficiently prepare for the activities.
- While a mini-parliamentary roundtable was completed, a full roundtable is planned for after the 2017 elections.
- The HCV report has almost been completed, with summary translations still required prior to dissemination. However, a more targeted dissemination plan is required to make this a more meaningful activity.

While partners felt that there was still a lot of work that is needed, most were in agreement that they could complete their activities before the end of the project. Having said that, MAC noted that it is currently in the process of recruiting a new project manager, given that their previous manager for this grant has left the organisation, and recruiting a new manager was important for ensuring that some activities could be completed, given that only one member of staff is currently working on this project.

With regards to progress against the country-based logframe targets, Malaysia has either achieved or is on track to achieve most of the targets by the end of 2016 (Table E.2).

Table E.2: Malaysia's progress against country-based logframe targets at end 2016[25]

Indicator	2016 milestone	Results at end of 2016
P1: % Official policymaker support	2/10	Milestone exceeded (7/2)
O1.1: % Achieved annual targets achieved	5/7	Milestone met (5/5)
O2.1: # PLHIV-PLHCV events	8	Milestone met (8/8)

[25] Note that the indicators for number of events for drug users and PLHIV-PLHCV refer to the same activities.

Indicator	2016 milestone	Results at end of 2016
O2.1: # HCW events	3	Milestone note achieved (0/3)
O2.1: # Drug user events	8	Milestone met (8/8)
O2.2: Targeted policymaker meetings	32/66	Milestone almost met (26/32)
O2.3: Mass media pieces	6	Milestone exceeded (19/6)

Source: UNITAID (2017).

C+ project management

Partners noted having been in relatively frequent contact with C+, who provided useful support to develop advocacy materials for community-based programmes, including educational posters/ flyers on DAAs.

While it was noted by one stakeholder that it would have been better for C+ to have a member of staff based in the region, the main project partner did not feel that this was necessary and would not have had a significant impact on the project's implementation. Rather, most partners felt that the CPM was useful for supporting in-country activities.

Budget management

While C+'s project management was generally commended, some partners noted delays in fund disbursements affecting activities, particularly given the relatively small size of organisations and inability to cover expenses through other funding sources. It was recognised that this was largely a result of funding being delayed from UNITAID to C+, as opposed to funding disbursements being delayed from C+ to partners. Further, some partners noted that budget management could be quite burdensome at times, with the requirement to request to C+ for any change in activity/ budget lines.

E.1.5. Results and sustainability

The main project achievement in Malaysia has been the increased commitment by key government officials regarding access to DAAs, with many stakeholders noting the government now being on the right track to issue a CL for sofosbuvir and having shown some commitment to doing so in the near term. Notably, HCV was discussed in parliament on 8th March 2017, with the Minister of Health stating a working paper was currently in development regarding issuing a CL for sofosbuvir. Whilst this commitment is due to a range of factors, many noted the important work of the country partners in building this commitment.

With regards to other HCV drugs, a number of stakeholders noted that in-country partners were directly involved in ensuring that the application for DAC's data exclusivity was rejected.

Awareness raising work with communities to develop action plans has also started to see some positive results. For example, advocacy to the Muslim Council has led to direct funding

to purchase DAAs through buyers' clubs. Furthermore, this activity has empowered community groups to advocate for change, with nine patient groups signing a letter to the MoH regarding pending patents for sofosbuvir and velpatasvir. Additionally, a strong commitment has been made by local generic manufacturers to produce DAAs and activities are already underway to prepare the ground for registration once a CL has been issued.

A number of stakeholders also noted the project having been important for bringing the project's CSOs together in a coordinated fashion, with one voice. For example, prior to this project, TWN and MAC rarely worked with each other.[26]

While it is difficult to attribute the effects of this project to these emerging results, it is widely agreed that without the support of the project, Malaysia would not have made this level of progress. This project has allowed the CSOs to have dedicated advocacy staff, particularly for MTAAG+ and MAC who have staff members wholly funded by the grant.

While the progress and experience of the project in Malaysia has generally been positive, almost all stakeholders felt it was unrealistic to expect outcomes and goals of the project to be achieved before the end of this year. There are a number of activities which need to be completed before a more widespread HCV treatment programme can be implemented, which will require continued advocacy efforts, these include:

Before a CL is issued, a number of processes need to be undertaken and key stakeholders need to be kept on board if this commitment is to be maintained. Key areas of focus should include:

- Ensuring commitment from the broader cabinet and the Ministry of Domestic Trade, Cooperatives and Consumerism, who will be responsible for approving and then formerly issuing the CL respectively.
- Advocating for a CL of sufficient duration, given the CL for HIV medicines was only valid for two years.
- Ensuring continued government commitment to in spite of anticipated pressure from Gilead and the US Chamber of Commerce.

In general, although all stakeholders commended the work of the partners and believed the work was highly relevant, most did not think that 18 months was a sufficient amount of time to expect the results that are being set by the project.

[26] It should also be noted that MAC and TWN had not previously working together partly due to personal differences between senior staff. However, staff have changed since the start of the project.

E.2. Thailand

E.2.1. Background

Country burden and key issues

It is estimated that around 1.9m people live with HCV in Thailand, although as at 2016, less than 2,000 patients (0.1%) were receiving treatment.

Table E.3Table E.2 outlines the three ways to access health services in Thailand.

Table E.3: Thai health service access

Health scheme	Eligibility	Population coverage	Hep C services
Central health benefits scheme	Government employees	8%	Included
Social security scheme	Formal employment	12%	Not included
Universal health scheme (30 Baht scheme)	Rest of population, provided through the National Health Security Office (NHSO)	73%	Peg-interferon included, but only part of diagnostics costs reimbursed

Generally, the political climate towards HCV in Thailand is positive. For example, there are national targets on coverage and there is awareness within government that action is required. Whilst HCV services are included in the universal health scheme through peg-interferon, the following barriers to accessing treatment remain:

- Cost represents the main barrier, with a course of Harvoni treatment costing $4,500.
- Diagnostic costs for all four tests are US$260 -$725, of which US$290 is reimbursable. A fibroscan is also required, although there are only 14 machines in Thailand.
- Treatment can only be prescribed by an internal medical specialist. Full treatment course can only be completed in Bangkok, requiring travel and accommodation costs for those outside the capital.
- Discrimination in the health service towards PWID.
- Low level of HCV awareness in the general population.

Drug licensing situation

There is a patent pending for sofosbuvir, with stakeholder views differing as to how likely it is that this will be approved. There is currently a fairly strong movement to push the government to reject the patent. The Thai government has a high capacity in terms of IP knowledge. Therefore, technical assistance is not required.

The Thai Government Pharmaceutical Organisation had produced sofosbuvir locally, although, this was then blocked by Gilead. Whist there is high local generic manufacture

capacity, Thai IP laws mean that Gilead could retroactively claim for losses if a patent is approved.

Stakeholders felt that there was strong political willingness to include DAAs in the essential medical list. The Health Interventions and Technology Assessment has conducted a cost-effectiveness assessment of DAAs with peg-interferon, which shows cost-effectiveness of DAAs, although it is unclear what DAA price was included.

There are several semi-organised buyers' clubs operating in Thailand and these are seen as a viable interim approach in order to raise public awareness.

E.2.2. Project start-up

C+ initially visited Thailand in November 2015, with further visits in December 2015, January 2016 and June 2016 to identify partner and plan activities. A contract was then signed in September 2016, six months' later than planned, although actual project implementation did not begin until December 2016, meaning a nine month delay for the start of activities. This was due to an error in the details provided by the Thai bank, meaning that funds were not accessible. Both C+ and project partners reported having made significant efforts to rectify this situation.

Project partner choice

C+ initially began project discussions with several partners, including:

- **AAF** - one of the leading Thai experts on IP and trade negotiations, with a reported ability to influence policy makers through established relationships. Several stakeholders reported that this organisation would have been the most relevant lead partner.
- **TNP+** - an advocacy and lobbying organisation with a focus on access to treatment, training of people living with HIV and AIDS as peer educators, and experience of buyer's clubs.
- **TTAG** – Currently conduct one other project, working with prisoners in Northern Thailand. They have worked on HCV issues for more than 10 years, having published a paper on the hidden epidemic of HCV in 2014.
- **Ozone** – Focus on PWID, with an established network which reaches approximately 90% of this target group (3-4m IUD/year). It is estimated that around 90% of PWID have HCV. Ozone began working on HCV in 2013, due to a strong demand from clients. In a survey on priorities, clients named HCV as the top issue they would like Ozone to work on, with HIV issues coming in seventh place. Whilst they are strong on service provision to PWID, advocacy is not seen as being a key organisational strength.

AAF and TNP+ decided not to continue with the project and C+ then signed contracts with TTAG and Ozone.

This final partner selection in Thailand has been a missed opportunity. Whilst the work of the two implementing partners appears to be relevant, the range of activities are not sufficient to affect change, with a focus only on grassroots empowerment of marginalised groups and lack of activities relating to direct policy influencing.

There are several highly relevant partners in HCV advocacy, including for example Treat Asia, APN+ and the Asia Network of People who use drugs. These organisations have been involved in relevant activities currently underway, including challenging Gilead's patent request, direct price negotiations with policy makers, or attendance at the UN Collective Efforts on Affordable Medicines held a meeting, which included a strong focus on DAAs. However, C+ were not able to bring these partners into the project due to:

- **Perceived lack of clarity on project aims**, objectives and approach by partners during the project development phase, which discouraged key partners, AAF in particular, to be involved. This was also as some felt C+ was too prescriptive on the project approach.[27]
- **Lack of capacity from C+** at the beginning of the project, due to small staffing numbers during project negotiations, leading to slow communication and furthering partner concerns over lack of project clarity and trust in C+ to deliver. There was a view that the project had been too ambitious at the start relative to capacity, with too many countries included initially, thus reducing the overall project impact.
- **High transaction costs** of developing and preparing the project in terms of activity selection and developing a suitable project timetable, relative to the potential amount of support available.
- **Short proposal development timeframe**, particularly in relation to the internal resources available of potential country partners.

E.2.3. Project relevance and design

Project activities were jointly chosen between C+, TTAG and Ozone. However, C+ wanted a greater focus on direct advocacy, whereas both partners conduct advocacy only through empowering PWID clients and enabling their voice to be heard.

Project implementers now feel that the project design will not lead to the planned objectives of building a national network of PLHCV, with a longer timeframe required and a need to redesign activities, due to, for example:

[27] We also note that AAF had funding from other sources for HCV-related activities.

- Only one meeting was planned for each support group to raise awareness on Hep C, with no budget for follow-up meetings.
- National advocacy meetings had been planned without any pre-meetings for each of the groups travelling to Bangkok in order to agree a common message or activism strategy.

Whilst project activities are *relevant*, they will not be *sufficient* to achieve the overall project aim, given the sole focus on community empowerment. Partners lack knowledge on fundamental project aspects around IP and drug licensing, and need strong technical support to ensure that activities are meaningful and impactful. Further, the approach adopted is unlikely to affect change within the timeframe of the project and will require a much longer project of three to five years. Therefore, either additional partners should have been chosen or the project approach should have been changed. There is a mismatch between the project aims and objectives (common across countries) and the approach adopted in Thailand.

E.2.4. Project implementation

Project progress

Project activities have been implemented since December 2016, although teams have only been recruited since January, nine months behind schedule. These delays have been due to:

- Bank transfer, due to incorrect codes being provided by the bank, resulting in the project only commencing at the beginning of December. Both C+ and partners made considerable efforts to rectify this issue with the bank.
- Due to lack of possibility to back charge no activities were started until beginning of December.
- Recruiting staff has taken longer than expected.

In terms of activity completion, of the eight sites where PWID clients will be made aware of HCV issues, only three have currently been implemented. It is unclear whether the project will be able to fully implement activities now within the timeframe, with some feeling this is possible and others noting it will be a significant challenge. However, with only eight months remaining on the project, this leaves limited time for such activities to have any real impact.

This project is not bringing any real value-add to changing the policy environment in Thailand in the short term. However, it is ensuring that civil society is part of the voice to change the policy, but the impact of this will require a much longer funding commitment.

Project targets were decided jointly between C+, TTAG and Ozone. Whilst these targets are achievable, there will be challenges given delays. Details regarding how the Thailand country programme has performed relative to its 2016 milestone is provided in Table E.4 below.

Table E.4: Thailand's progress against country-based logframe targets

Indicator	2016 milestone	Results at the end of 2016
P1: % Official policymaker support	1/2	Milestone not achieved (0/1)
O1.1: % Achieved annual targets achieved	6/8	Milestone almost met (3/6)
O2.1: PLHIV-PLHCV events	3	Milestone not achieved (0/3)
O2.1: Drug user events	2	Milestone almost met (1/2)
O2.2: Targeted policymaker meetings	1/2	Milestone note met (0/1)
O2.3: Mass media pieces	2	Milestone note met (0/2)

Source: UNITAID (2017).

As the table shows, the programme is performing relatively poorly in terms of achieving the targets set within the logframe, largely due to the late starting of the project. However, given the project partners and their approach to activities, the logframe indicators are not fully relevant for Thailand. For example activities for indicator "O2.2: Targeted policymaker meetings" relate to community activists presenting a letter to a government official during a conference, rather than the more targeted activities being implemented in other countries. As such, the standard project monitoring and reporting approach does not fit for Thailand.

Project partners are confident that internal coordination is working well amongst the senior Bangkok-based staff. This is conducted through *ad hoc* meetings. However, additional funding has been requested to enable broader coordination with project staff based in regional sites to facilitate lesson learning.

There is no formal coordination mechanism for those involved in HCV in Thailand. Given the wide range of actors in-country who are not involved in this project, it would have been relevant to include a strong coordination element to the project, to ensure alignment, lack of duplication and relevance for the project.

There is limited awareness of project activities by other stakeholders and appears to be limited engagement with partners in terms of requesting technical support. Stakeholders felt that the project needed to increase its visibility in order to be more effective.

C+ project management

There have been communication issues between project partners and C+, mainly due to language difficulties. This has resulted in a range of misunderstandings, leading to some degree of frustration, including around budget management processes.

There is a long internal process required for all communication, with emails from C+ being first translated by a consultant, then jointly discussed by both TTAG and Ozone on how to

respond, the consultant would then draft a response, which needs to be vetted by the team before responding. This adds significant delays to communication.[28]

The perceived lack of flexibility by project partners in C+'s approach to project management has created some frustrations with partners, who noted other donors providing a much greater degree of autonomy.

Budget management

The process to finalise the project budget was lengthy, although this was mainly due to numerous discussions between project partners and it was agreed that C+ could not have acted to speed this process up.

Given around US$20,000 cost savings from the start of staff salaries, as well as an awareness that project activities had not been effectively designed, TTAG requested to realign the budget in the first progress report and proposed a range of activities. However, these were not approved by C+, given that C+ was unclear on what TTAG wanted to use this budget for.

Generally, there appears to be a poor understanding by partners of budget rules and procedures. For example partners understand that accommodation costs can only be charged for the number of days of a meeting, when lack of daily flights require participants to stay longer. However, UNITAID provide full flexibility to C+ to manage country grants and C+ policies allow accommodation costs to be charged for the full time spent away from home.

TTAG and Ozone have told C+ that unless they are either able to secure additional funding or be able to re-programme the budget to programme activities by June 1st, they will be unable to continue with the project.[29] This is due to two main risks that TTAG and Ozone consider the current project approach to have:

- Given the lack of follow-up activities provided to the community support groups, there is a risk that clients will view the organisation negatively.
- There is a project expectation of direct advocacy by CSOs to policy makers. However, this is not an approach typically adopted by TTAG or Ozone, who work to empower communities to advocate directly. If this advocacy to policy makers is done by TTAG/ Ozone directly rather than through their clients, there is a risk of losing trust with clients who feel that their voices are not being correctly represented.

C+ has advised that the additional activities proposed by partners to address the issues related to community support groups are not relevant to resolving these. It is therefore

[28] We understand that since the evaluation visit, communication has started to improve, with some direct communication between C+ and English-speaking partner staff.
[29] We understand that since the evaluation visit, project partners have communicated to C+ their ability to continue with the project.

unclear how this issue is being resolved, although C+ does have the authority to approve such a request given it is within budget categories.

E.2.5. Results and sustainability

Project results in Thailand to date include:

- Mobilising clients at three (out of eight planned) sites, with increased awareness on HCV and accessing services, as well as empowerment activities to increase voice.
- Ozone have been trying to get involved in HCV activities for four years and this is the first time funds have been received. This therefore legitimises Ozone's voice within the HCV space.
- During the first workshop, the team jointly agreed on the main relevant issues for PWID to be included in the policy paper. Whilst this workshop was helpful to raise awareness within project members on IP issues, it was not sufficient to train them to a standard by which they would be able to train project clients. The second workshop will not be sufficient to achieve this either.

There was strong agreement that a continuation of the project was required. Were the project not to be extended, there would be limited sustainability of results, with an increase in awareness of Hep C treatment amongst a specific target group.

However, we believe that several changes to project design would be required in a follow-on phase:

- A broader range of partners, with technical knowledge and ability to influence government
- Clearer strategy, including how this project complements the work of others
- A longer timeframe is required to affect change with this advocacy approach
- Stronger focus on data – without strong data, it is difficult to influence decisions. As such, a rapid assessment to show HCV prevalence would be important

Global Fund anticipate that HCV activities will figure in the current round of proposals.

E.3. Morocco

E.3.1. Background

Country burden and key issues

Morocco has an estimated HCV prevalence of 1.2-1.6%. While previous estimates suggested the disease burden may be as high as 3%, a national-level HCV prevalence study for the general population has never been conducted.[30] Data gathered through the MoH, WHO and World Bank estimated viremic infections in 2014 at 268,000 people although more recent estimates suggest the population is closer to 400,000 people.[31] The CDA Foundation estimates that there are 9,216 new infections per year and the National Strategic Plan to fight viral hepatitis notes a prevalence of 60% amongst PWID.

Table E.5 outlines the three health insurance schemes in Morocco.

Table E.5: Moroccan health service access

Health scheme	Eligibility	Population coverage	Hep C services
RAMED (Régime d'Assistance Médicale)	Informal workers, prisoners, orphans, unemployed and other vulnerable people	30%	Peg-interferon/ Ribavirin is covered, with 1,500 patients treated 2013-2016. Diagnostics are not covered, with costs estimated at US$245 for screening, Fibroscan and RNA testing.[32]
CNSS (Caisse Nationale de Securité Sociale)	Private sector employees	35%	Sofosbuvir included in the list of reimbursable drugs
AMO (Assurance maladie obligatoire)	Public sector employees/ retirees	34%	Sofosbuvir/ Daclatasvir included in the list of reimbursable drugs

The key issues in the HCV landscape in Morocco include:

- **Lack of HCV awareness:** There is a general lack of awareness about HCV and medical professionals are not actively testing patients.
- **Limited access to diagnostics:** Many patients are required to pay the high costs of diagnostic testing themselves. Diagnostic facilities are concentrated in Casablanca and Rabat, such that it is difficult for remote patients to access.

[30] A new prevalence study has been designed and is due to be launched once funding is identified.
[31] Ministère de la Santé, Royaume du Maroc (2016). « Plan Stratégique National de Lutte contre les Hépatites Virales, 2017-2021 ».
[32] Estimated costs provided by in-country stakeholders.

- **Costly treatment:** Morocco produces DAAs domestically (Pharma5 and Galenica). However, the costs remain high and unaffordable, and are significantly higher than those seen in India.[33]

Despite the above issues, Morocco benefits from engaged stakeholders across government. Consultees noted that the King of Morocco and MoH recognise the importance of fighting viral hepatitis. A draft National Strategic Plan to fight viral hepatitis was completed in late December 2016, although there have been delays in the approval process given the lack of government between October 2016 and April 2017. The previous Minister of Health has now been reappointed, with stakeholders confident that the National Strategic Plan will shortly be approved.

Drug licensing situation

Gilead did not request a patent for sofosbuvir in Morocco, such that there are generic DAAs produced domestically by Morocco's Pharma5 and Galenica pharmaceutical companies. Sofosbuvir has been locally manufactured since December 2015 and daclatasvir since April 2016.

Pharma5 is Morocco's largest generic company and has been operating for approximately thirty years. Pharma5 began producing sofosbuvir at the request of the Government. The CSO community then encouraged Pharma5 to produce daclatasvir. Pharma5 sells a course of treatment at US$756 for sofosbuvir and US$324 for daclatasvir, with Galenica selling at around US$50 cheaper.[34]

E.3.2. Project start-up

C+ originally undertook a country visit to Morocco in June/ July 2016 to understand the country context and meet with key partners. Given the presence of the Association de Lutte contre le SIDA (ALCS) in Morocco (a founding member of C+), C+ were able to undertake a single mission to both assess country suitability and conduct strategy analysis, rather than two separate missions. A contract was signed in September 2016, one month behind schedule due to staffing constraints in Morocco and that August is typically a holiday month.

Project partner choice

C+ initially selected two partners to work on the project, each bringing their individual strengths to the project:

- **ALCS:** a well-connected HIV organisation, with experience of carrying out HIV advocacy campaigns over nearly three decades and an extensive network that provides community-based treatment services. ALCS is responsible for 80% of HIV

[33] Coalition PLUS (2016). "Coalition PLUS HIV/HCV drug affordability project: Country Assessment Report and Work-Plan, Morocco".
[34] Costs provided by Pharma5 in Euros during in-country visit and converted into US$.

testing in Morocco through its health centres and mobile clinics. Since 2014, ALCS introduced HCV diagnosis, treatment and advocacy into its package of services, although its ability to intervene in the HCV landscape has been limited by funding. ALCS is well-connected with Government and were a key partner in developing the National Strategic Plan for viral hepatitis. The President of ALCS, Professor Hakima Himmich, is the current chair of C+.

- **ITPC-MENA,** one of the eight regional networks of ITPC Global, focuses on advocacy, capacity building, monitoring access to treatment and community-led research activities. ITPC-MENA is led by Othoman Mellouk, an internationally respected intellectual property and access to medicines expert who is very well-connected in Morocco. ITPC-MENA has a reputation of challenging Government on health issues (versus ALCS who often promote a more collaborative image of working with Government) and is well-connected with media outlets across Morocco.

These two organisations are highly relevant for the project, given their range of expertise and complementary advocacy styles. Stakeholders noted ALCS being the best-placed CSO in Morocco for the work given (i) its on-the-ground experience with HIV and HCV diagnosis, (ii) its more than two decades worth of experience of advocacy work, and (iii) its connections across the highest levels of Government. Given the strengths of ALCS, it is not immediately clear why ITPC-MENA was also included in the project initially, other than to leverage the network of Othoman Mellouk, particularly with media outlets. However, ITPC-MENA has decided not to continue with the project as of end February 2017 to focus on other work (e.g. ongoing work for UNITAID on HIV) and ALCS is now the sole in-country partner leading the work. As such, ALCS have redesigned some activities for 2017 (discussed below).

Other key organisations involved in advocating HCV-related issues include:

- **Association de Lutte Contre les Hépatites** – a small, newly created volunteer-based organisation. It uses the ALCS model to work on HCV issues, although, we understand that ALCH is reluctant to work openly with ALCS given the stigma associated with HIV, although the organisations coordinate well.
- **Collectif pour le Droit à la Santé au Maroc** – A coalition of several NGOs working across public health (e.g. pharmacists, health workers, labour unions, etc.) with the objective of defending equality, equity and access to public health services. They are a strong partner for disseminating documents across the public health field.

E.3.3. Project relevance and design

ALCS staff in country, as well as Othoman Mellouk from ITPC-MENA, were responsible for designing the programme alongside C+. Our understanding is that most activities were proposed by and intended to be led by ALCS, with only a small handful being proposed by ITPC-MENA for them to then lead. Since the design of the programme however, ALCS has

become the sole project partner and is implementing all activities, having made some changes to those originally intended to be led by ITPC-MENA, including:

- Planned community advisory boards, which would advocate to generic manufacturers to lower prices through engaging with Egyptian/ Indian generics, will no longer continue under the project, although ITPC-MENA will implement with other funding.
- Planned benchmark study on DAA pricing (which ITPC-MENA will continue outside of the project) has been changed to a study on diagnostic pricing (to be completed by ALCS).
- Planned monitoring report has been changed to a policy paper on inclusion of harm reduction activities as part of the implementation plan for the National Strategic Plan on viral hepatitis.

Stakeholders in Morocco all agreed that the project is relevant and will continue to be so for the foreseeable future given the degree of government buy-in and the engagement of reputable organisations in the space (WHO, ALCS, ITPC-MENA, etc.). The departure of ITPC-MENA from the project was not viewed as significant by stakeholders, with ALCS confident they can complete all activities themselves. Coordination between the two partners remains strong.

E.3.4. Project implementation

Project progress

At the time of C+'s 2016 Annual Report, Morocco had completed six of the ten planned activities. Delays were attributed to the fact that a cabinet had not been agreed and accordingly, parliament had not sat since the elections in October 2016. However, as shown in Table E.6, progress has now been made against all ten activities, as well as most of the additional six activities envisaged.

Table E.6: Activity progress to date

Activities	Progress
Core activities	
Activity 1: HCV Coordination meetings between partners (one every three months)	An HCV coordination meeting was held in 2016 and another was held in early 2017.
Activity 2: Seminar in the Parliament	A seminar has not been held in Parliament yet given that Parliament was not in session for six months. Still, one meeting has been held with parliamentarians and ALCS is in contact with the second chamber of parliament and has a designated contact there. As part of the seminar, ALCS intend to advocate for a dedicated budget line for HCV and to remove barriers to

Activities	Progress
	accessing to HCV treatment.
Activity 3: Meeting with the DGAPR and the reintegration of prisoners association	ALCS have had a number of meetings with DGAPR as a result of their ongoing contract outside of the project to provide information services, testing and treatment services for HIV and HCV in prisons.
Activity 4: Advocacy meetings with the epidemiological office of the MoH and persons in charge of the National Strategic Plan	ALCS has held advocacy meetings with the epidemiology team within the MoH and are supporting the development of the Implementation Plan.
Activity 5: Community advisory board	This activity will be continued by ITPC-MENA, although outside of the project.
Activity 6: Hepatitis C CSOs demand paper	This work has been fully completed.
Activity 7: Written pledge to be signed during elections campaign (2016)	This work has been fully completed. ALCS coordinated a pledge to be signed by various CSOs to lobby government on issues of HCV during the 2016 election. Eight political parties publicly agreed to these demands.
Activity 8: Radio spots and interviews to (a) encourage people to get tested and to promote RTDs, (b) demand effective universal access	A radio recording in Arabic has been prepared in full and ALCS must now roll it out across radio networks. ALCS noted that they had registered a radio spot and were preparing for the launch of the recording.
Activity 9: Benchmark studies on DAAs and diagnostics prices and on test pricing + Press conference to market the studies	This was one of the activities originally proposed by ITPC-MENA. Given that there are already benchmarking studies existing and in progress on DAAs (e.g. ITPC-MENA are carrying out a regional benchmarking study on the price of DAAs), ALCS have prioritised the benchmarking of diagnostic prices. To date, ALCS have drafted terms of reference for the recruitment of a consultant to carry out the benchmark on the price of tests for diagnostic and follow-up examinations for viral hepatitis C. We understand that they intend to launch the call for tenders during the week commencing 17th April 2016.
Activity 10: Monitoring report on harm reduction activities	This was one of the activities originally proposed by ITPC-MENA. ALCS will now prepare a policy paper to include a harm reduction package in the NSP Implementation Plan. ALCS have drafted terms of reference for the identification of gaps in PWID harm reduction activities. Once the study is rolled out and results are collected, ALCS will be in a position to lobby government on these issues.
Additional activities	
Activity 11: Investment case on economic returns should Morocco decide to treat HCV (adaptation of	This work is in process. Consultants from Pharos Health have been hired by C+ to carry out the investment case work, which is expected to be finalised by September 2017 with

Activities	Progress
our international investment case) and corresponding seminar to "market" the investment case	emerging findings by July 2017.
Activity 12: Development of a treatment manual and brochures (targeting HCW, PLHCV, and other communities)	This activity is in progress. A treatment manual and brochures are currently being developed in Arabic.
Activity 13: Advocacy coordination meeting with partner NGOs	ALCS have established an advocacy platform with partner NGOs and a joint advocacy letter has already been sent by the group to encourage the approval of the National Strategic Plan.
Activity 14: Conferences during health professionals' seminars	This activity has yet to take place.
Activity 15: Production of content on HCV for the ALCS' website	This activity is complete. ALCS have created a dedicated viral hepatitis section of their website: http://www.alcs.ma/hepatites
Activity 16: Creation of a mainstream website on HCV	ALCS have developed an HCV-specific website that connects to its main website, although this mainstream website has not yet been launched in the public domain.

The M&E framework for Morocco was developed jointly by C+ and ALCS. As regards country-based logframe targets, Morocco has seen mixed progress against several of these targets (Table E.7).

Table E.7: Morocco's progress against country-based logframe targets[35]

Indicator	2016 milestone	Results at end 2016
P1: % Official policymaker support	3/19	Milestone exceeded (9/3)
O1.1: % Achieved annual targets achieved	7/10	Milestone almost met (6/7)
O2.1: Drug user events	5	Milestone not achieved (0)
O2.2: Targeted policymaker meetings	25/85	Milestone almost met (10/25)
O2.3: Mass media pieces	6	Milestone not achieved (1)

Source: UNITAID (2017).

Whilst Table D.3.3 reports few of the indicators having been met, this does not seem to accurately reflect the positive project progress to date. A key reason for this is due to delays linked to lack of government cabinet. However, it is not clear which activities are linked to creating the media pieces.

While Morocco does not appear to have made good progress against country-based logframe targets as of yet, it was clear during the country visit that the appropriate parties

[35] Note that the number of events for drug users and PLHIV-PLHCV refer to the same events, hence why these numbers are the same.

are engaged in the project and that ALCS is making good progress with its envisaged activities. The lack of a parliament for six months has affected the progress of some activities, such as a workshop with parliamentarians, but has not impacted other engagements with policymakers or Government's participation in such things as the investment case.

C+ project management

Generally, C+ project management appears to be working well. ALCS noted that they have been in frequent contact with C+, citing numerous teleconference but ALCS also noted that these conference have always been of value. ALCS did note that the 16-month timeframe for the work is very tight and insufficient, as well as commenting on the long length of time to develop and design the project.

Budget management

ALCS did not note any major issues with C+ budget management and stated financial resources being sufficient. The only comment with regards to budget management was that it appears to be very rigid, leaving limited flexibility for changes over time.

E.3.5. Results and sustainability

Project partners played a key role in developing the National Strategic Plan to fight viral hepatitis prior to project start, which has placed them in a strong position to influence the design of the implementation plan. Partners are in agreement that engagement with government partners has worked well during the project's implementation, despite the lack of a Minister of Health for six months. Various stakeholders have noted that Morocco is at an important juncture in its addressing of HCV, with the correct players all engaged such that well-articulated and well-organised advocacy work has the potential to be very influential. Further, the investment case currently being developed is likely to be strong advocacy tool in terms of encouraging a dedicated budget line.

ALCS have successfully rolled out HCV programming alongside and using the channels designed for its HIV programming. ALCS have also introduced HCV testing and access to treatment in prisons, which is identified as being a high-risk group. There are also a set of awareness raising activities planned, including creating a website, developing brochures and broadcasting a radio advert, which have potential to achieve results.

The project has established a CSO platform in March 2017, which has already sent a joint letter to the Government regarding commitment to the National Strategic Plan for viral hepatitis.

ALCS noted being able to do "infinitely less" without the project support. Whilst ALCS would retain a focus on HCV even without project support, this would have to be done using HIV-related budgets and without dedicated staff to lead activities, likely resulting in less structured activities.

E.4. D.4 Colombia

E.4.1. Background

Country burden and key issues

Out of a population of 48m, nearly 410,000 people (0.9%) are estimated to be living with chronic HCV. Of the total estimated HCV population, nearly 89% are estimated to be genotype 1, followed by genotype 2 and 3. Despite this estimated prevalence, only 996 people were treated for HCV in 2015.

Colombia has a universal health system with formal sector workers and their families covered through mandatory enrolment onto the public health insurance scheme (although public sector and companies can be part of special schemes). Individuals living under the poverty line are covered under a scheme called the Subsidised Plan (covering 38% of the population). While access to healthcare has recently improved under the Subsidised Plan, certain expensive drugs are not covered. In addition to these two systems, there are over 60 private insurance companies who have an influential role in the health system, given that they can assign patients healthcare facilities and decide whether certain treatments can be covered.

Government spending on treatment is beginning to have a significant impact on the health system in Colombia, with an estimated 50% of the health budget being spent on medicines due to high drug prices. The wider cost of medicines issues is having an impact on the treatment of HCV, with a number of insurance companies not encouraging HCV diagnosis for fear of becoming bankrupt if they are required to pay for expensive drugs.

The government's commitment to diagnosing and treating HCV is articulated under the National Health Plan for Hepatitis 2014-17, which covers all forms of hepatitis, as well as in their approval of the WHO Global Health Sector Strategy on Hepatitis. According to some project stakeholders, the government is currently in the process of developing HCV guidelines.

Drug licensing situation

Colombia was not included in either Gilead or BMS's VLs, and both sofosbuvir and daclatasvir are patented in the country. According to C+'s Country Assessment Report and Workplan, no price was set for sofosbuvir at the time of writing since it was not registered in the country, although our country consultations suggest that people receiving DAA treatment in Colombia have required US $30,000 as part of payments claims through the judicial process. For daclatasvir BMS were charging US$35,000 for 3 months of treatment. Around 17 patent applications relating to sofosbuvir and daclatasvir were either pending or granted when the country programme began. As Colombia is a signatory to the TRIPs Agreement, it is required to provide patents for a 20-year period. In addition, Colombia is required to provide and data exclusivity for a five-year period.

Recently, Colombia has partnered with other countries in the region as part of the UNASUR-PAHO price negotiations for DAAs, which according to stakeholders would result in sofosbuvir treatment costing US$4,500 and combinations with ledipasvir and daclatasvir costing around US$7,000. However, these prices would still be unaffordable to launch a national HCV programme in Colombia, and therefore are only seen as a stop-gap measure.

Colombia has had some experience issuing CLs, including a recent issuing for imatinib, a cancer drug provided by Novartis. However, this has not been a straightforward experience for the country and has faced significant opposition from its trade partners, particularly the US given fears that it may issue future CLs for drugs provided by US companies (particularly HCV drugs).

E.4.2. Project start-up

C+ undertook initial country visits in May 2016 with CSOs and other in-country partners to gain a better understanding of the situation in the country and identify the most appropriate partners. An additional follow-up mission was undertaken in June/July 2016. Following contract negotiation and signing as well as the finalisation of the country workplan, country activities in Colombia were officially launched in October 2016, one month ahead of schedule.

Project partner choice

Following these visits and through remote consultations, C+ identified Fundacion Ifarma (hereafter Ifarma) as the appropriate implementing partner for Colombia, given its position as one of the leading organisations working on access, use and quality of medicines in Colombia. In addition, Ifarma asked the government to make a declaration of public interest concerning HCV in November 2015, demonstrating their commitment to addressing hepatitis C. While Ifarma is the only formal Colombian partner under this project, it has a long history of working with Mision Salud, a CSO focused on issues associated with access to medicines, and Liga Sida, a community-based organisation with 25 years of experience working on HIV. Both organisations will support the activities related to this project on an informal basis, reflecting the previous approach that the organisations have taken when working together, which C+ has been able to leverage for this project.

Based on the above, it appears that C+ have selected the most relevant partner to work with in Colombia, given its background in advocating for improved HCV treatment as well as its interaction with government and other CSOs that can complement its activities.

E.4.3. Project relevance and design

Stakeholders agreed that this project is highly relevant in Colombia and noted that a multi-pronged approach to advocacy (to both government and community stakeholders) as relevant to address the key country issues. While other disease areas (such as cancer and the Zika virus) are a key concern of the government, HCV is also seen as an important issue.

In particular, the MoH is very concerned with the high price of DAAs in the country and would like to take measures to significantly reduce this price before a national programme with DAA treatment can be implemented. In addition, stakeholders noted that there is significant demand from different regions in the country for HCV to be addressed and that testing should be increased, and partners are concerned that this may not be met.

Ifarma and C+ jointly designed the project activities, which include to:

1. Organise a forum of experts (specifically aimed at doctors and HCWs) to exchange information about HCV.
2. Produce and disseminate education and mobilisation material, which would be disseminated as part of country mobilisation meetings.
3. Facilitate communication and information exchange between civil society networks, which includes setting up coordination meetings and workshops between key partners to garner support for wider project campaigns.
4. Conduct workshops aimed at leaders of civil society from the country's main cities, who belong to groups such as PWID, PLHIV, PLHCV, PLHIV-HCV and other vulnerable populations.
5. Implement a communication and advocacy campaign on access to treatment targeting MoH, parliamentarians, insurances, healthcare workers, CSOs and patient groups' networks.
6. Mobilise legal work targeting Colombian Patent Office.
7. Pilot collaboration with progressive health insurance organisation with Savia Salud.
8. Advocacy meetings with relevant stakeholders, such as MoH and other relevant departments.

With regards to the above, country stakeholders noted that these activities are suitable given that they capture a wide range of areas and ensure that one aspect of advocacy work is not pursued at the expense of others.

E.4.4. Project implementation

Project progress

Since the project commenced, Ifarma has been active in implementing its activities, with six planned activities completed out of the eight activities identified above (activities four and five were not planned to be implemented during the reporting period).

Areas of activity that are worth a particular note are Ifarma's work in mobilising local communities, where it has been able increase the level of awareness and demand in patient organisations and others, which has resulted in these organisations engaging further with local health authorities and doctors on how access to treatment can be improved.

Considerable progress has been made to implementing the magistral drugs pilot programme, which will allow a small number of patients to access DAAs from local pharmacies for personal use at as little as US$300. However, it should be noted that this is not expected to take place on a large scale, given the limited ability to reach a wide number of patients using this approach and the inability to promote this on a large scale given the patents in place.

Ifarma has also been involved in high-level meetings related to improving treatment to HCV drugs in the region. Of particular note is the high level meeting at UNASUR on World AIDS Day, where different countries decided that a regional strategy to addressing the situation of HCV drug affordability should be addressed, an international declaration of public interest for HCV should be declared and national programmes for hepatitis should be developed.

In general, the country programme has been able to meet a number of logframe targets, despite it only being active for a relatively short period of time. Details of progress in relation to logframe targets for 2016 is provided in Table E.8 below.

Table E.8: Colombia's progress against country-based logframe targets

Indicator	2016 milestone	Results at end 2016
P1: % Official policymaker support	3/18	Milestone met (3/3)
O1.1: % Achieved annual targets achieved	4/6	Milestone exceeded (6/4)
O2.1 HCW events	5	Milestone almost met (3/5)
O2.2: Targeted policymaker meetings	6/22	Milestone almost met (3/6)
O2.3: Mass media pieces	9	Milestone almost met (8/9)

Source: UNITAID (2017).

It should be noted that events targeted at drugs users and PLHIV-PLHCV were not included in the country programme as they were not seen as necessary despite original inclusion in the logframe. Further, additional events for HCW were also not seen as necessary after the first three were implemented.

While the above logframe does suggest progress has been reasonable in Colombia, this does not capture several activities which stakeholders noted as being particularly relevant. For example, the project's efforts to mobilise community support for HCV nor the pilot programme on magistral drugs is incorporated into the logframe, both of which were noted by country stakeholders as important additions to the project.

C+ project management

Ifarma have welcomed the support of C+ and believe that they have been useful with regards to discussing appropriate project activities. Nevertheless, Ifarma noted that there have been some conflicts with regards to how the project should be administered, with Ifarma preferring a more flexible approach to implementing each of the project activities, while C+ would like to see a more strict and systematic approach put in place (although

Ifarma note that this is a requirement of UNITAID as opposed to C+). In addition, Ifarma have found that budget changes can take a long time to be processed and approve (in some cases up to a month), which has meant that they have had to go ahead with activities before approval is given so that activities are not delayed. C+ have noted that such delays were due to clarifications being requested by UNITAID.

Budget management

Ifarma noted that going forward, it would like to see an increase in its budget to meet demands of local organisations to campaign on behalf of the project, given that current resources are not sufficient to cover these activities.

E.4.5. Results and sustainability

While the wider project results have not yet been achieved given the project has only been operational for six months, the issue of HCV treatment costs is on the government's agenda (particularly in MoH), and the work of Ifarma through the project has contributed to this. This follows Ifarma advocating for a declaration of public interest for HCV (a first step for the country issuing a CL). While this took place before the Colombia programme commenced, stakeholders noted that the support of this project has allowed Ifarma to continue its advocacy work in this area.

Ifarma has also began engaging with universities and research institutes on implementing a pilot programme that uses magistral drugs to cure HCV patients, allowing them to have access to treatment for as little as US$300. Some stakeholders also noted that having this project has placed HCV right at the top of Ifarma's agenda, which may not have been the case in the absence of C+'s involvement.

In addition, the project's awareness raising efforts outside of government have been noted as being an important result of this project, and would not have been possible in the absence of C+'s support.

While stakeholders were positive about the project's progress, a full HCV treatment programme is unlikely to be implemented in the near term, with many believing this is unlikely to happen within the next two to three years. One immediate barrier is the patents currently in place for key HCV drugs. While there is commitment by the MoH to address these barriers, other departments are less interested in seeing these removed given the recent experience with imatinib. It is viewed that issuing a CL could have an impact on wider trade with the US, as well as impacting Colombia's application to join the OECD. Given these issues, Ifarma should focus its efforts under activities five and eight on these departments, which includes the Ministry of Trade, the Planning Office and the Office of the President, which stakeholders noted were particularly opposed to issuing a CL.

Despite the achievement of results within the project timeframe being unlikely, stakeholders noted that momentum is being built around the project and that in the absence of C+ support this momentum is unlikely to be sustained.

ANNEX F C+ RISK MANAGEMENT FRAMEWORK

Table F.1 provides a summary of the key risks identified at C+ during different stages of the project and suggested mitigation measures.

Table F.1: Risks identified by C+ at different project stages

Report	Risks identified	Mitigation measures
Phase 1(a) Project Plan	1. Job market risks resulting in inability/delays in recruiting project staff. 2. Inability to seek advisory input due to availability and logistical issues. 3. Limited availability of CSOs in-country or inability of C+ to engage effectively. 4. Burden of activities could result in little time for documentation to be finalised.	1. Exploit multiple channels of recruitment, using hiatus period to manage delays, using existing C+ resources and consultants if staff not recruited on time. 2. Plan meetings and send invites early, whilst also utilising remote resources. 3. Shortlist CSOs before visits, allow sufficient time to meet all partners during visits and clarify in agreements that signing of contracts are output of Phase 1(a), and that C+ is empowered to negotiate them. 4. Continuously work on documents in a light-touch manner whilst working more heavily around key project dates, avoid starting discussion from scratch by appending tentative Phase 1(b) plan to original grant agreement and plan workshop with UNITAID to plan Phase 1(b) one week after finishing Phase 1(a).
2016 Semi-Annual Report	1. Cheap drugs not getting to where solvent demand is. 2. Prices remaining unaffordable, which in turn limits demand ("chilling effect"). 3. Rapidly evolving environment.	1 and 2. Reducing prices or providing access to cheap drugs is the objective of the project. 3. Strategy adaptation and evolution will be discussed with partners, with experts and activists throughout the project.
Phase 1(b) Project Plan	**Project outcome risks** 1. Cheap drugs not getting to where solvent demand is. 2. Prices remaining unaffordable, which in turn limits demand ("chilling effect"). **Strategic risks** 1. Global ART coverage plummeting, which in turn reducing the relevance of HIV/HCV co-infection.	**Project outcome risks** Mitigation measures not identified. **Strategic risks** 1. C+ will discuss with UNITAID about re-orientating the project towards addressing reduction in ARTs. 2. C+ will discuss with UNITAID possibility of refocusing project on addressing high demand and need to realign supply.

Report	Risks identified	Mitigation measures
	2. Large countries such as China and India making HCV their first free nationwide treatment programme. 3. Global pandemic breaking out which results in HCV being de-prioritised. **Implementation risks** 1. Local CSOs showing little interest in project. 2. Raising expectations in local CSOs during the assessment visit. 3. Country partners failing to perform awareness campaigns despite C+ support. 4. Fraud, conflict of interest and conflicts. 5. HCV intervenors, advocates or regulators being unwilling to coordinate. 6. Reduction in project countries. 7. Delays in implementation due to understaffing. 8. Currency fluctuation losses. **Sustainability risks** 1. Phase 2 funding fails to be secured. 2. Recruitment of human resources in project countries. 3. World Health Assembly rejects Global Hepatitis Strategy, or makes a determination to de-prioritise hepatitis within SDG 3.3. 4. Rapidly evolving project environment.	3. Discuss grant amendment with UNITAID. **Implementation risks** 1. Consider level of local activism as part of country choice. 2. State clearly to CSOs the nature of visits and be transparent about process of engagement. 3. Undertake careful assessment of CSOs capacity and ability to freely operate. 4. Undertake investigations of partners, undertake fiduciary assessments and include references to all conflicts of interest in contract. Fraud and conflicts to be addressed as part of manual of procedures. 5. Held preliminary discussions with intervenors, utilise support of key CSOs to garner support from advocates and maintain regular communication with the relevant partners. 6. C+ hire sufficient staff to ensure country programmes managed effectively. 7. Problems were expected to be alleviated with hiring of key staff, but if this was not the case the issue would be discussed with UNITAID. 8. Use past project savings to overcome exchange rate losses. If this is not possible, cost extension can be discussed. **Sustainability risks** 1. Start discussions on phasing for following phases 10 months early. Risk would have been mitigated by partners' improved capacity with regards to implementing project and connections with authorities and wider international network. 2. Clarify the timeline of funds and ensure short-term contracts are implemented. 3. Ensure event is used to fully mobilise commitments to HCV. 4. Discuss evolution and strategy adaption with experts on the project.
2016	1. Distrust and suspicion towards international & foreign	1. Present project as a tool for in-country CSOs as opposed to imposing C+'s

Report	Risks identified	Mitigation measures
Annual Report	organisations. 2. Political instability, elections and changes in MoH personnel in project countries could slow down dialogue in government. 3. Difficulties linked to long-distance management and the respect of SOPs. 4. Risk of micro-managing the partners' national work. 5. War on Drugs in South East Asian countries could affect work of partners in the region. 6. Delays and difficulties recruiting staff in country.	views on partners. 2. Intervene with key government and political partners throughout key events, whilst also fully utilising political connections whilst they are strong. 3. Increase number of CPM to manage country programmes, C+ work more with partners where project management is an issue and provide technical expertise to partners. 4. Maintain hands-off relationship with partners whilst providing technical support when needed. 5. C+ advocate against negative effects of War on Drugs through discussions and reports, while in-country partners maintain close relationship with government. 6. Hire consultants where deficiencies found, whilst also increasing responsibility of junior staff.

Source: C+ (2015; 2016; 2017)