

Lessons Learnt: The MSF governance model of the UNITAID Grant “Ensuring access to the HCV treatment - revolution for HCV/HIV co-infected patients in LMICs”

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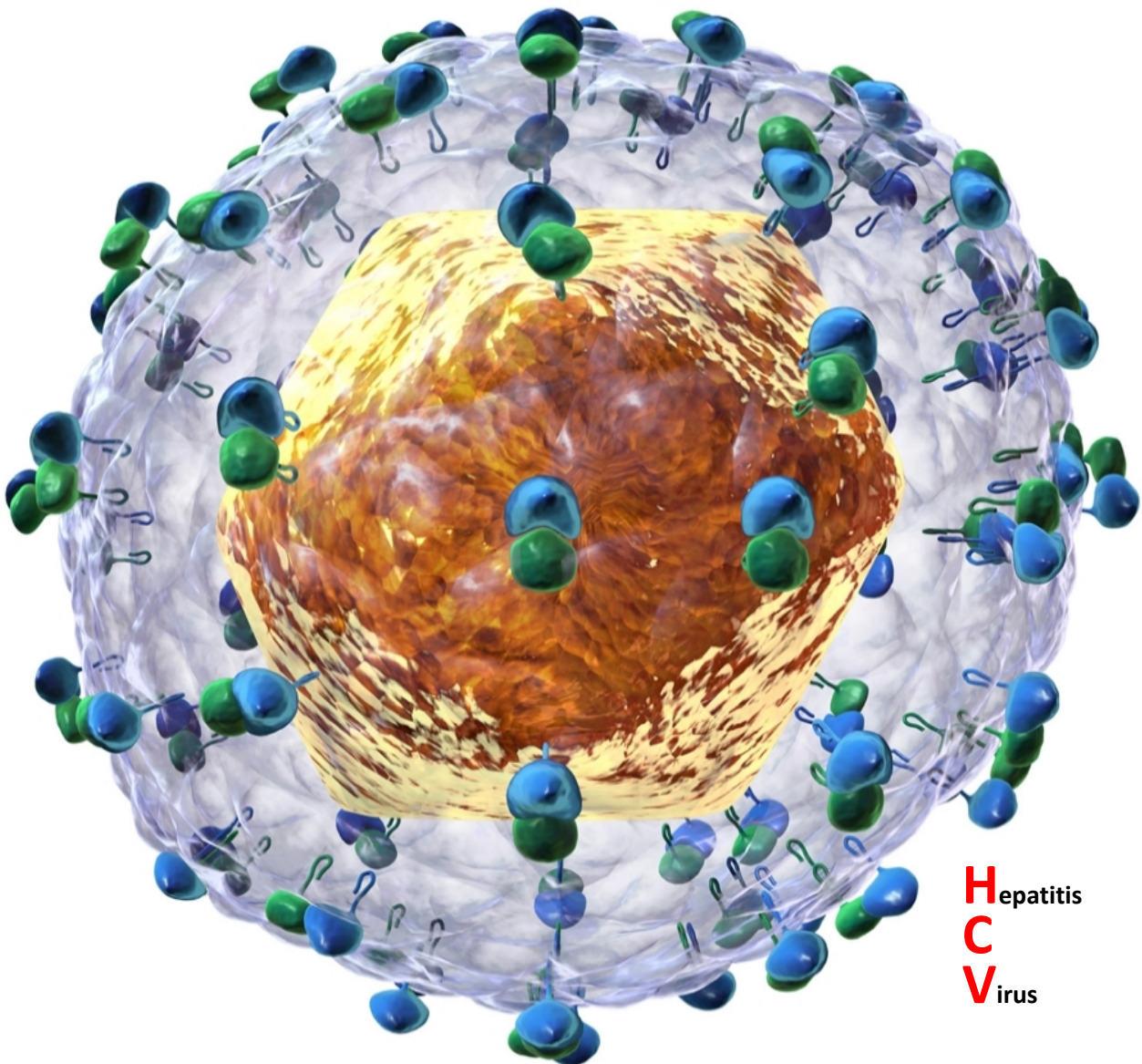


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Executive summary

This report is a lessons learnt exercise of *Médecins Sans Frontières* (MSF) governance model of the UNITAID Grant for HCV/HIV co-infected patients in low and middle income countries. The assignment was carried out by Hugues Juillerat, Sharon McClenaghan and Glenn O’Neil of TRAASS International and was commissioned by the Operational Centre Geneva (OCG) of MSF. The exercise was carried out from June to September 2018 through interviews with 45 MSF staff and project stakeholder and a review of project documentation.

Findings

Achievements: The UNITAID grant enabled MSF to test and introduce a new and more effective and accelerated treatment for thousands of HIV/HCV infected patients. The number of patients screened and enrolled was lower than the set targets, partially explained by changes to the countries selected. 61% of available grant funds were used with 73% of screening target met.

The pricing of the drug treatment for HCV dropped by 99% during the project’s duration. This dramatic reduction was not only due to MSF’s advocacy but also to market forces and costing studies. Referencing project data, the 2018 WHO guidelines on HCV recognized the combination of the medicines sofosbuvir (SOF) and daclatasvir (DCV) as a pan-genotypic treatment. An activation of the Ministries of Health (MoH) in the project countries on HCV was seen and also provided an opportunity to address the situation of hepatitis B (HBV). The Access Campaign (AC) legally challenged the patents of HCV medicines in several countries. The grant encouraged a joint approach to HCV within MSF and contributed to an increased interest in HCV externally. MSF’s questioning of the co-infection approach of the grant, also contributed to UNITAID’s internal reflections on this approach.

Management and set-up: The project set-up was based on a central point within MSF, the UNITAID Pool, that coordinated all the activities related to the grant with the different components within MSF. The role played by the HCV Contact Group was not envisaged but was a main support for the UNITAID Pool and helped in coordination and motivation across MSF. The MedOps, the decision-making body of the OCs operational and medical directors, also played a role in setting the overall policy for collaboration with UNITAID.

Strategic decisions: The strategic decisions in 2013 included the agreement within MSF to accept funds from UNITAID, increasing the focus on HCV, the cross-cutting nature of the project and the selection of countries. These decisions were seen as essential in order to qualify for the UNITAID grant and secure “buy-in” for the project within MSF. In its initial implementation (2015-16) it became apparent that prevalence of HIV/HCV co-infection in the selected countries was lower than estimated in the grant proposal. As a consequence, several countries were dropped and several added. This delayed the project’s implementation but was seen as essential to ensure that the funding was used appropriately. In 2017, UNITAID accepted MSF’s proposition to treat HCV mono-infected patients in Cambodia. The 2018 negative decision of UNITAID for a no-cost extension required MSF to review which activities it would continue or not, which varied depending upon the type of activities.

Catalytical role: The UNITAID grant did have a catalytical role in increasing interest in HCV within MSF and externally and contributing to simpler and cheaper treatment beyond those

patients directly treated. At the same time, there was considerable debate within MSF as to the extent of the catalytical change triggered by the grant; For example, it is likely that without the grant MSF would have anyway increased its treatment of HCV. However, the development of the range of common MSF practices and policies would have been unlikely to have happened without the grant.

Potential of set-up: The governance and management set-up used for the UNITAID grant was found to have potential for future MSF interventions. It was assessed that such a set-up would be suitable for future interventions with certain characteristics, such as being intersectional with a common strategy and focused on a particular medical issue that goes beyond direct patient care. The potential of the set-up would also be conditional on having in place a central and funded coordination position, a cross-sectional technical support group, documented roles and responsibilities and common monitoring and reporting.

Conclusions and discussions

MSF met successfully the goals and outcomes of the project despite the adjustments needed in the project's implementation (country selection) and the considerable underspend –39% of available funds were not used. Considering that the project was integrated within existing MSF HIV projects, the cost-effectiveness aspect deserves highlighting. The holistic approach of the project that went beyond direct treatment brought considerable results that will benefit potentially HCV infected patients worldwide. There was a catalyst role of the grant, even if the extent of this role is debated. Nevertheless, there was general consensus that the grant did accelerate MSF's actions on HCV and in it adopting a common and "joined-up" approach for HCV. It was found that the involvement of an external donor and partner (in this case UNITAID) was a key trigger for such a common approach.

The governance and management set-up largely facilitated the achievements of the project with some limitations identified, mostly linked to the diverse elements of the project proving it challenging for communications at time for all involved. Strategic decisions essential for the project or for adaptation to the context were taken. In this regard, both UNITAID and MSF showed flexibility in adapting the grant to match where the greatest needs were.

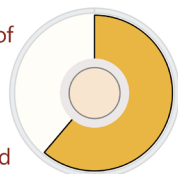
With UNITAID funding for MSF's HCV work finishing, it is anticipated that MSF will continue with many aspects of the project; the long-term impact of the grant will be seen as the simplified models of care and cheaper treatments will be rolled out in other countries. As of September 2018, UNITAID's new strategy for HCV remains to be defined but it is hoped it will build on the achievements to date in HCV of this and other projects.

Lessons were identified in the areas of project strategy, management set-up and working with donors (see p. 17).

Lessons Learnt: The MSF governance model of the UNAID Grant "Ensuring access to the HCV treatment revolution for HCV/HIV co-infected patients in LMICs"

PROJECT & GRANT FACTS

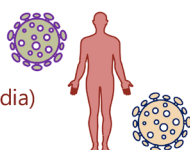
61% of available grant funds were used



The UNAID funding for this project commenced in **January 2015** and ceased in **June 2018**



Limited to **co-infected** HIV/HCV - (except Cambodia)



Coverage (7 countries)

South Africa
Mozambique
Kenya
Pakistan
India
Myanmar
Cambodia



ACHIEVEMENTS



Drug treatment price dropped by **99%** during the project's duration.



The 2018 **WHO guidelines on HCV** recognized the combination of the medicines sofosbuvir (SOF) and daclatasvir (DCV) as a pan-genotypic treatment.



An **activation of the Ministries of Health (MoH)** in the project countries on HCV was seen.



The grant **encouraged a joint approach** to HCV within MSF and contributed to an **increased interest in HCV** externally.

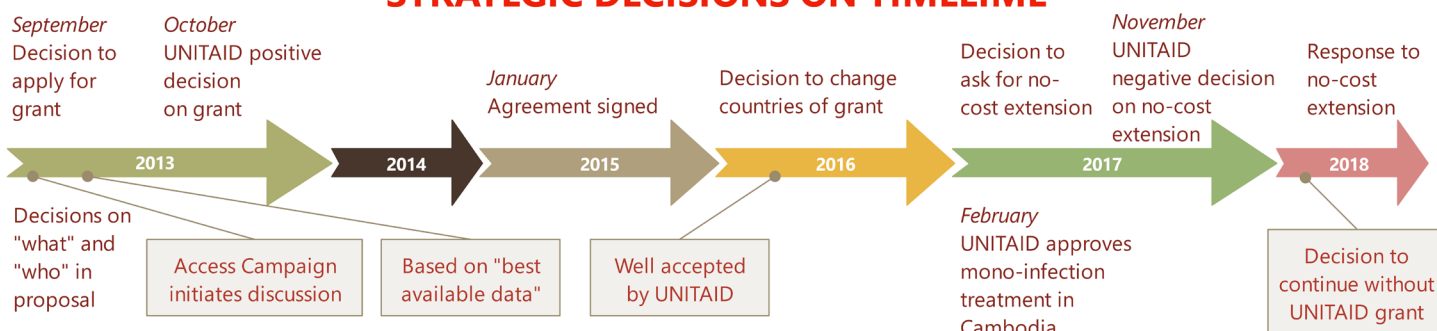
The Access Campaign (AC) legally **challenged the patents** of HCV medicines in several countries.



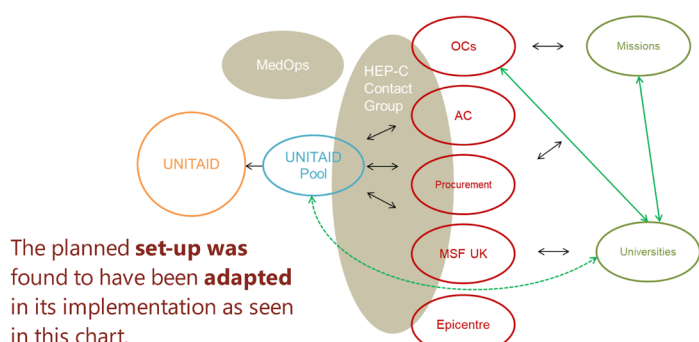
73% of screening target met the grant fund.



STRATEGIC DECISIONS ON TIMELINE

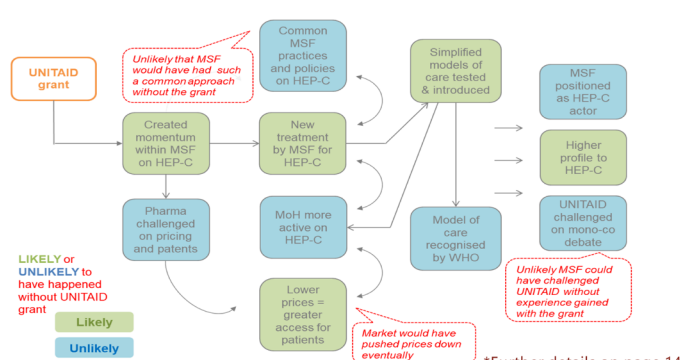


KEY STRATEGIC DECISIONS



*Further details on page 11

CATALYTIC ROLE OF THE GRANT



*Further details on page 14

Abbreviations

AC	Access Campaign
CEA	Cost-effectiveness Analysis
DAAAs	Direct Acting Antivirals
DCV	Daclatasvir
HBV	Hepatitis B
HCV	Hepatitis C
IR	Inception Report
MSF	<i>Médecins Sans Frontières</i>
MoH	Ministry of Health
OCA	Operational Centre Amsterdam
OCB	Operational Centre Brussels
OCBA	Operational Centre Barcelona Athens
OCG	Operational Centre Geneva
OCP	Operational Centre Paris
SOF	Sofosbuvir
ToR	Terms of Reference
VEU	Vienna Evaluation Unit

1 Introduction

1.1 Background

This report is a lessons learnt exercise of *Médecins Sans Frontières* (MSF) governance model of the UNITAID Grant for HCV/HIV co-infected patients in low and middle income countries. The assignment was carried out by Hugues Juillerat, Sharon McClenaghan and Glenn O'Neil of TRAASS International and was commissioned by the Operational Centre Geneva (OCG) of MSF.

With the support of USD 13.6 million grant from UNITAID, in 2015 MSF set up screening and treatment of HCV/HIV co-infected patients in 8 sites in 7 countries within existing MSF HIV projects, and carried out related operational research, legal and regulatory work as well as advocacy. MSF estimated that the total costs of these HIV projects were USD 48 million with the UNITAID grant contributing some 30% of the costs. The UNITAID funding for this project commenced in January 2015 and ceased in June 2018. The grant was led by OCG and implemented in collaboration between Epicentre, Access Campaign (AC), four OCs (OCB, OCG, OCP, OCA and MSF UK), Imperial College and University of Bristol.

1.2 Objectives and purpose

The objective of this lessons learnt exercise was to assess the advantages and disadvantages of the UNITAID grant governance and management model for:

- Project achievements in terms of medical (and related) outcomes;
- Strategic decisions;
- The potential for collaboration between multiple MSF entities and to leverage the learnings for replication in the future projects.

The purpose of this exercise was to capitalise the main achievements of the project, to document lessons learnt and good practices.

The time period covered by this assignment was January 2015 to June 2018.

1.3 Methodology

The three external evaluation consultants of TRAASS International worked for 20 days from June to September 2018 to conduct this lessons learnt exercise. The tasks were carried out through two main methods:

- Semi-structured interviews and discussions with 45 MSF staff and project stakeholders;
- Review of available documentation.

A list of persons interviewed is found at annex 5.2; a list of the main documents consulted at annex 5.3; the Inception Report (IR) at annex 5.4 and the Terms of Reference (ToR) at annex 5.5.

1.4 The Limitations

The inception report (IR) set out three anticipated limitations and how these would be countered. These limitations did not prove to be a major obstacle for the assignment as following:

- The period of the data collection falls in July/August, so availability of the stakeholders may be limited due to the holiday period.

Mitigation strategy: Interviews will be requested with the stakeholders over an extended period of time (late June until early September).

Result: Interviews were held until early September with the majority of stakeholders available.

- As a part of lessons learnt, causal links (i.e. cause-effect relationships) between governance set-up, strategic decisions made, and project achievements will need to be established. This requires professional judgement and involves potential biases.

Mitigation strategy: The causality will be challenged during the interviews, and more than a single informant will need to express similar opinion to verify the causal links. Interviews with the key informants will be held by more than one consultant so the judgements will be formed by the team and will be reviewed jointly.

Result: The evaluation team examined any suggested causal links carefully and considered the different points of view.

- The UNITAID Grant covered a broad range of activities implemented by at least eight MSF entities/partners. Information on the implementation and consequent achievements may therefore be spread across these entities/partners and could be difficult to access.

Mitigation strategy: Contact will be established with all known participating MSF entities/partners. Further, a snowballing sampling approach will be adopted (i.e. asking interviewees to recommend other potential interviewees) to ensure that the maximum number of stakeholders are reached.

Result: The evaluation team interviewed representatives of each MSF entity and reached further stakeholders through suggestions from interviewees.

2 Findings

This section details the findings of the lessons learnt exercise based on the objectives as described above. Annex 5.1 shows the pathway from findings to conclusions and lessons identified.

2.1 Main achievements

As an indication of the project's achievements, it was successful in meeting its global goals and outcomes over its three-year duration¹:

<i>Project goal and outcome indicators</i>	<i>Target</i>	<i>Result</i>
Number of countries with guidelines that include screening and treatment with direct acting antivirals (DAAs)	4	4 Cambodia, Myanmar, India, South Africa
Number of countries with at least one Ministry of Health-run site implementing new WHO guidelines and/or MSF models of care for screening and treatment	5	5 Myanmar, India, Cambodia, Kenya, South Africa ²
Number of simplified HCV models of care tested for implementation in diverse resource limited settings	3	3 HIV co infection (Manipur-India & Dawei-Myanmar); general population urban setting (Phnom Penh); intravenous drug users (Nairobi)
Number of countries in which a Cost-effectiveness Analysis (CEA) was developed and completed	5	4 Cambodia, Pakistan, Kenya, Myanmar

Meeting its goals and outcomes were further reflected in the achievements identified in the following project aspects:

Medical: The UNITAID grant enabled MSF to introduce a new and more effective and accelerated treatment for thousands of HIV/HCV infected patients as seen in the progress made on the select medical indicators below. A simplified model of care was tested and

¹ As defined in the project logframe; reporting data provided by MSF. Targets were estimations at the start of the project.

² The project was also implemented in Mozambique.

introduced. Although the number of patients screened and enrolled were lower than the set targets, this is partially explained by the changing of the intended treatment countries (see section 2.3) and illustrated by the underspend of the grant (61% of available funds were used³). At the same time, with these funds, 73% of screening target were met.

<i>Select medical indicators</i>	<i>Target</i>	<i>Result</i>
Number of patients screened per site	68'250	73% 49'829
Number of active HIV/HCV infected patients enrolled in MSF sites	1830	72% 1310
Numbers of patients initiated on DAA treatment per site	2308	95% 2'199
Cure rates (per MSF site, calculated as "per intention to treat")	70%	87%

Advocacy: The pricing of the drug treatment for HCV dropped by 99% during the project's duration: from some USD \$50,000 to \$100. This dramatic reduction was not only due to MSF's advocacy but also to market forces and costing studies according to persons interviewed. Nevertheless, it was thought that the AC's focus on HCV, pricing and access did accelerate the price drop.

Based on MSF project data from Cambodia and South Africa, the 2018 WHO guidelines on HCV⁴ recognize the combination of the medicines sofosbuvir (SOF) and daclatasvir (DCV) as a pan-genotypic treatment. According to the guidelines, this treatment:

*"(...) presents an opportunity to simplify the care pathway by removing the need for expensive genotyping and so simplifying procurement and supply chains. These regimens offer a major opportunity to facilitate treatment expansion worldwide"*⁵.

The increased attention given to HCV by MSF contributed to an activation of the Ministries of Health (MoH) in the project countries. For example, in Myanmar, the MoH have drafted an HCV policy. In Mozambique, the MoH has included HCV (and HBV) diagnosis and treatment for HIV co-infected patients in the 2017 funding proposal to the Global Fund. MSF's involvement in HCV provided it with an opportunity with MoH to address the situation of hepatitis B (HBV), for example in Cambodia and India.

Legal: As part of the project, the AC challenged the patents of HCV medicines through a legal process in several countries: key patents on Sofosbuvir were rejected in Egypt and Ukraine,

³ Funds used (2015-2017) (USD): 7,064,340; Closure funds used (2018): 1,232,240; Total funds used (2015-2018): 8,296,580; Total funds available: 13,600,000. The grant ceiling was 14,900,00 and the last approved budget was 10,400,000.

⁴ WHO (2018). *Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection*.

⁵ Ibid, p. 24.

and decisions are pending or being appealed in other countries, including China, India, Argentina, Brazil, Russia and Thailand.

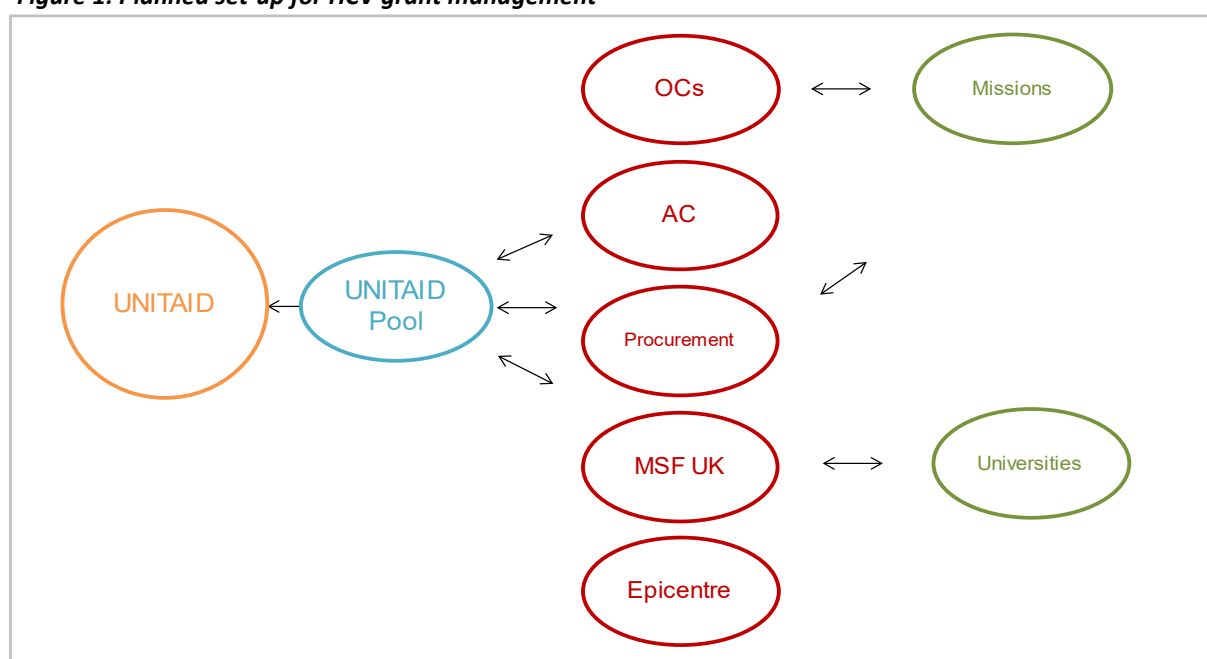
Broader achievements: The project also contributed to broader achievements as following:

- Within MSF, the UNITAID grant accelerated and encouraged a **common and joint MSF approach** to HCV. The project clarified the need for HCV referents in each OC, the establishment of an HCV contact group and creation of a common MSF strategic framework for HCV and an HCV patient database (managed by Epicentre).
- MSF's involvement in HCV through the UNITAID grant contributed to an **increased interest (or profile) in HCV** in general outside of MSF. The fact that MSF rolled out a global project across its movement did increase visibility and interest in HCV (e.g. from MoH, other NGOs, etc.) according to persons interviewed. MSF's involvement and its questioning of the co-infection approach of the grant (ineligibility of mono-infected patients), also contributed to UNITAID's internal reflections on this approach. The project also prompted more action and interest on HBV according to field staff interviewed.

2.2 Management and set-up

The grant governance and management set-up were described in the 2015 agreement between MSF (OCG) and UNITAID and supported by an inter-sectional agreement within MSF⁶. The set-up was based on a central point within MSF, the UNITAID Pool, that coordinated all the activities related to the grant with the different components within MSF, as can be seen in the chart below (Figure 1). The Pool also managed the other UNITAID grant (Viral Load).

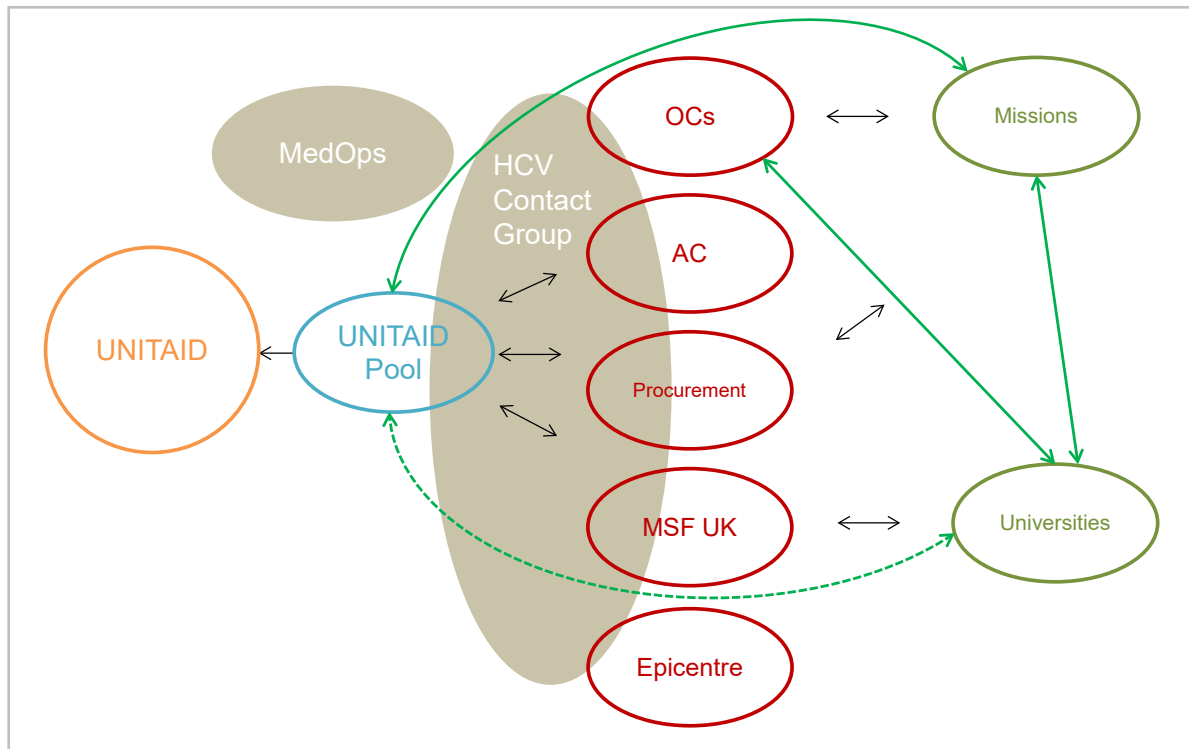
Figure 1: Planned set-up for HCV grant management



⁶ Annexes 1 (functional chart) and 2 (Roles and responsibilities) to the Grant Agreement (2015); Intersectional agreement on the use of the UNITAID funding for HCV (2015).

The planned set-up was found to have been adapted in its implementation as seen in the chart below (Figure 2).

Figure 2: Actual set-up for HCV grant management



The main differences, as identified by this lessons learnt exercise were:

- The role played by the HCV Contact Group was key to the successful management of the project. Made up of the HCV referents of each OC and HCV focal points of other entities, the Contact Group was not envisaged in the planned set-up but was a main support for the UNITAID Pool and helped in coordination and motivation across MSF.
- The UNITAID Pool had direct contact with the field missions and the universities to a lesser extent, mainly to facilitate the project reporting. At the same time, the universities and Epicentre needed to have direct contact with the field missions to carry out their research.
- The MedOps, the decision-making body of the OCs operational and medical directors, also played a role in setting the overall policy for collaboration with UNITAID, not only concerning the HCV grant but for the other two grants.

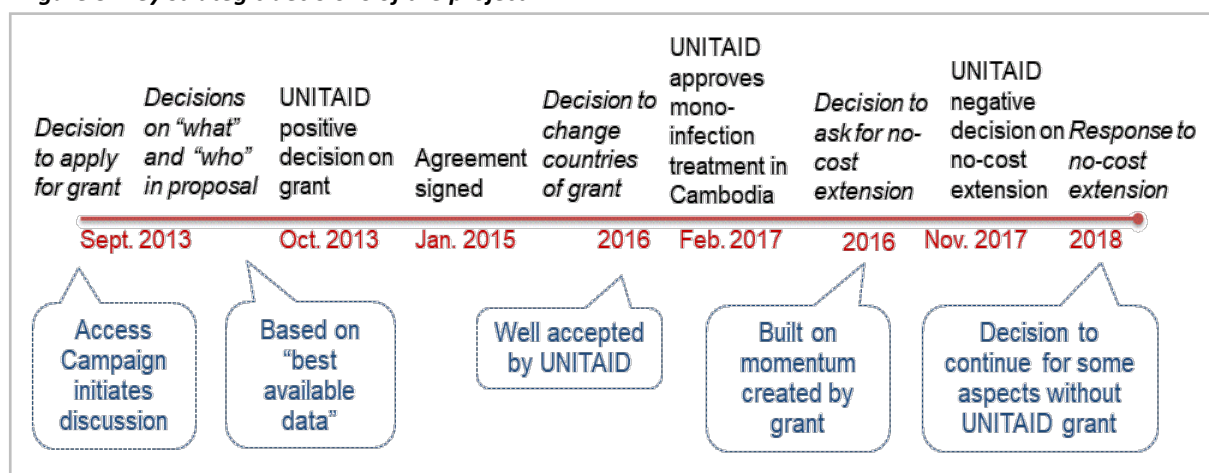
The following table describes which elements of the set-up were beneficial or harmful for the achievements of results:

Beneficial of set-up to achievements	Harmful of set-up to achievements
<ul style="list-style-type: none"> - The key coordinating role of UNITAID Pool facilitated the project for participating MSF entities. - The facilitating role of HCV contact group and referents supported the project. - The AC played an important role in giving visibility to HCV within and outside MSF. - The set-up encouraged links and common approach to HCV within MSF. - The consistent and constant support of the set-up provided a stability for HCV within MSF and built institutional support. - The existence of documented agreements between MSF entities on the roles/responsibilities was positive (If not known to all). 	<ul style="list-style-type: none"> - The set-up, global reach and different components of the project made it challenging for all to see the grant's "big picture". - There was limited communication on successes and milestones of the project within MSF (for both those involved and those not). - The operational research (universities) was lacking visibility amongst MSF entities; the other entities of the project had limited understanding of where it fitted in the project; what was its activities, deliverables and intended outcomes. - The project required reporting that was additional to regular reporting and a burden for some (i.e. field missions). - Some MSF entities thought that decision-making was too "top down", such as the selection of countries.

2.3 Strategic decisions

The following chart (Figure 3) sets out the key strategic decisions of the project as identified by this lessons learnt exercise, with some explanations:

Figure 3: Key strategic decisions of the project



The first set of strategic decisions (2013) involved important elements including the agreement within MSF to accept funds from UNITAID (decision taken by the MedOps), increasing the focus on HCV by MSF, the cross-cutting nature of the project and the selection of countries to be included. The selection was based on the best available data according to MSF staff. These decisions were seen as essential in order to qualify for the UNITAID grant and secure “buy-in” for the project within MSF.

In its initial implementation (2015-16) it became apparent that prevalence of HIV/HCV co-infection in the selected countries was lower than estimated in the grant proposal. As a consequence, several countries were dropped (Iran, Uganda, Ukraine) and several added (Cambodia, Pakistan and South Africa). This was well accepted by UNITAID but delayed the project’s implementation up to one year for some aspects, such as the operational research of the universities. These decisions were seen as essential to ensure that the funding was used appropriately (i.e. in countries with higher co-infection).

In 2017, UNITAID accepted MSF’s proposition to treat HCV mono-infected patients in Cambodia to increase the evidence base for the pan-genotypic use of SOF+DCV treatment, which was a deviation from the core focus of co-infection (in 2017, 2796 mono-infected patients were treated in Cambodia). For MSF, this decision was needed to support more robust medical evidence (which was ultimately used as supporting evidence in the above-mentioned WHO guidelines). MSF would have liked to extend the project to mono-infected patients in other countries, but this was not accepted by UNITAID.

The 2018 negative decision of UNITAID for a no-cost extension⁷ required MSF to review which activities it would continue or not. As the grant was funding multiple elements, this varied. For example, without UNITAID funding, the AC will find it challenging to continue its high focus on HCV; most of the patient treatment would continue using MSF’s own funds, although “delays and setbacks”⁸ were expected.

2.4 Catalytical role of the grant

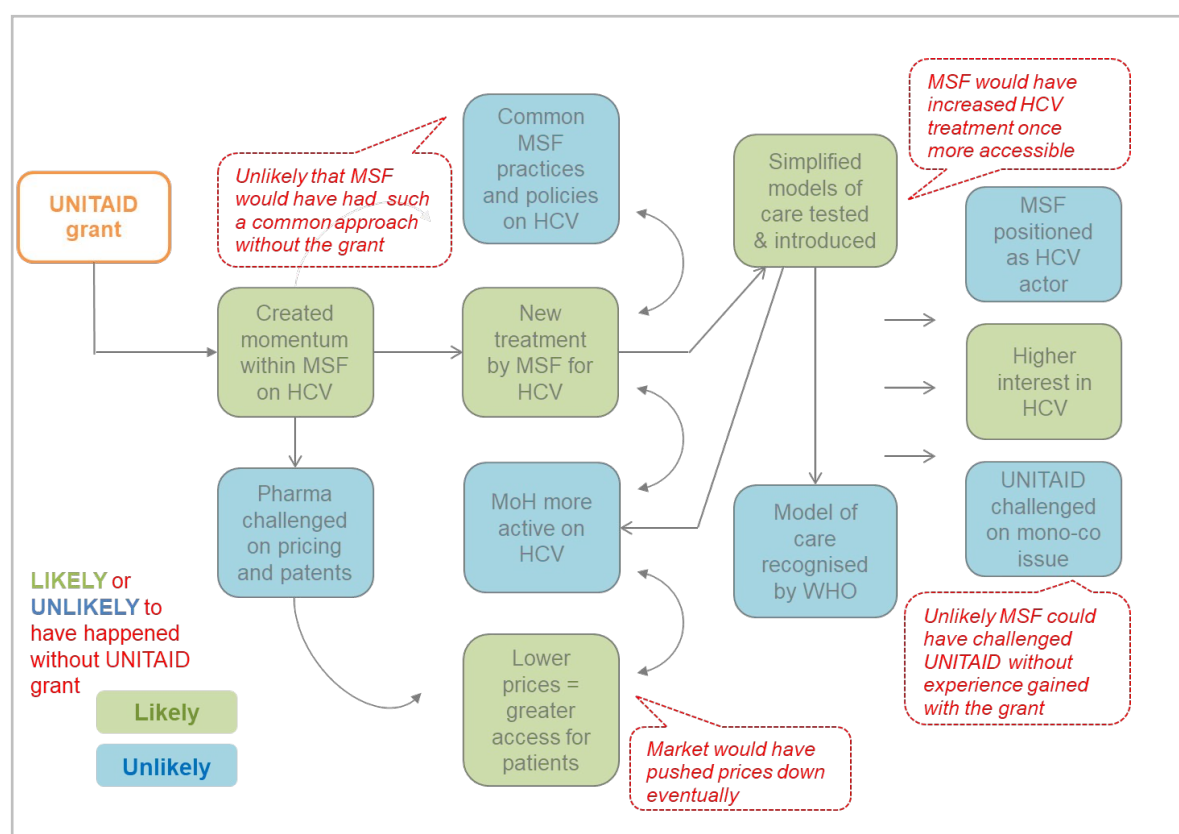
It was found that the UNITAID grant did have a catalytical role in increasing interest in HCV (within MSF and externally) and contributing to simpler and cheaper treatment beyond those patients directly treated by the project. At the same time, there was considerable debate amongst MSF staff interviewed as to the extent of the catalytical change triggered by the grant; the following graph (Figure 4) maps out the catalytical changes as identified by this lessons learnt exercise and estimates what would have likely or unlikely happened without the grant (red comment bubbles provide additional explanation).

For example, it was estimated that the development of the range of common MSF practices and policies on HCV and MSF’s consequent position as an HCV actor would have been unlikely to have happened without the grant. At the same time, it is likely that without the grant MSF would have anyway increased its treatment of HCV as there was a momentum on HCV building within MSF prior to the grant.

⁷ In its no-cost extension, MSF was requesting to use the remaining funds (47%) of the grant over the period of an additional year (2018). It was not a request for additional funds.

⁸ MSF, Annual Report 2017, HCV project.

Figure 4: Catalytic role of the grant



2.5 Potential of set-up

The governance and management set-up used for the UNITAID grant was found to have potential for future MSF interventions. It was assessed that such a set-up would be suitable for future interventions with the following characteristics:

- Interventions that are intersectional, with other MSF elements (e.g. AC, Epicentre) and/or external partners (it would not be appropriate to have such a set-up for a singular OC project);
- A focus on a particular (single) medical issue across MSF (rather than a range of issues);
- A medical issue that has opportunities that go beyond direct patient care (such as influencing global standards and policies; carrying out operational research to build an evidence body; etc.);
- A common intersectional strategy with objectives, targets and milestones is needed.

The potential of the set-up would also be conditional on the following aspects being in place:

- A central and funded coordination position (as seen with the UNITAID Pool);
- A cross-sectional technical support group (as seen with the HCV Contact Group);
- A documented definition of roles and responsibilities for the project;
- Agreement on common monitoring and reporting by all involved entities.

3 Conclusions and discussion

MSF met successfully the goals and outcomes of the project despite the adjustments needed in the project's implementation (country selection) and the considerable underspend – 39% of available funds were not used. Considering also that the project was integrated within existing MSF HIV projects, the cost-effectiveness aspect deserves highlighting.

The project delivered directly a new, more effective, simpler and much cheaper treatment to patients across seven countries. The holistic approach of the project that went beyond direct treatment also brought considerable results that will benefit potentially HCV infected patients worldwide. These include the drastically reduced costs of medicines, availability of simplified models of care, their validation by WHO, activated MoHs and greater interest in HCV in general.

Considering the above, this lessons learnt exercise concluded that there was a catalyst role of the grant, even if the extent of this role is debated within MSF. Nevertheless, there was general consensus that the grant did accelerate MSF's actions on HCV and in it adopting a common and "joined-up" approach for HCV. It was found that the involvement of an external donor and partner (in this case UNITAID) was a key trigger for such a common approach – by requiring uniform indicators, data, focal points, etc.

The governance and management set-up largely facilitated the achievements of the project with some limitations as identified above, mostly linked to the diverse elements of the project proving it challenging for communications at time for all involved. Strategic decisions were taken that were essential for the project or to adapt to the context. In this regard, both UNITAID and MSF showed flexibility in adapting the grant to match where the greatest needs were.

With UNITAID funding for MSF's HCV work finishing, it is anticipated that MSF will continue with many aspects of the project; the long-term impact of the grant will be seen as the simplified models of care and cheaper treatments will be rolled out in other countries, mostly led by MoH. As of September 2018, UNITAID's new strategy for HCV remains to be defined but it is hoped it will build on the achievements to date in HCV of this and other projects.

4 Lessons identified

The following lessons have been identified from this lessons learnt assignment that will be of potential interest for future projects:

Project strategy:

- ✓ A strategic approach for a project that goes beyond direct medical care can have wide-ranging impact for patients in the long term (thinking all who will benefit from the simplified and cheaper treatment and it's recognition by WHO).
- ✓ The strategy of cross-cutting projects should be conceived to exploit all possible synergies between the different elements in order to achieve maximum results (e.g. Linking patient treatment to operational research to building evidence for simplified medical protocols, policy change or radical drop of drug prices).
- ✓ A project strategy can recognise its potential to contribute to momentum that will have a wider impact, in this case such as the drop in drug prices, even if it cannot claim to be the only motivator for change.
- ✓ A project strategy can be successful where the medical element can easily integrate into an existing MSF treatment approach (as was the case for this grant). Introducing a new medical approach from a project strategy could prove challenging.

Management and set-up:

- ✓ In intersectional projects, there is a need for milestones / successes to be communicated so staff can see the “big picture” and ways of working together can be strengthened.
- ✓ In intersectional projects, a central coordinator can benefit markedly from a technical support group drawing from all MSF entities.
- ✓ Cross-cutting projects can prove even more beneficial to patients where the connections are made between the different project elements (e.g. field missions knowing of pricing discussions to support negotiations effectively at the national level).

Working with donors:

- ✓ Success was due partially to a consistent commitment to HCV across MSF necessitated by the grant. In absence of such donor funds that require a consistent and common approach, more thought will be needed to reproduce a similar joined-up approach.
- ✓ If MSF works again with donor funding it requires flexibility on both the side of the donor and MSF to adapt to the contextual needs (as was seen for this grant).

5 Annex

5.1 Findings, conclusions and lessons flowchart



5.2 Persons interviewed

	MSF Entity	Position	Location
1.	AC	Diagnostics Advisor	Geneva
2.	AC	Diagnostics Advisor	Barcelona
3.	AC	HCV referent (former)	Geneva
4.	AC	Head of policy and advocacy (former)	Paris
5.	AC	Head of Policy	Paris
6.	AC	Regional Head (South Asia)	New Delhi
7.	AC	Pharmacist	Geneva
8.	AC	Deputy Director	Geneva
9.	AC	medical advisor	Geneva
10.	AC	Medical Director (former)	Geneva
11.	Epicentre	Epidemiologist	Paris
12.	MSF Supply	Medical purchaser	Brussels
13.	MSF UK	Project Administrator	London
14.	OCA	APU purchases	Amsterdam
15.	OCA	Financial Operations (India)	Amsterdam
16.	OCA	Medical Coordinator	New Delhi
17.	OCA	health Advisor	Amsterdam
18.	OCA	Deputy Medical Coordinator	Yangon
19.	OCA	Medical Coordinator	Yangon
20.	OCA	Lab advisor	Amsterdam
21.	OCA	Operations Officer	Amsterdam
22.	OCB	HCV referent	Brussels
23.	OCB	Medical Coordinator	Nairobi
24.	OCB	Medical Coordinator	Cape Town
25.	OCB	Medical desk	Brussels
26.	OCB	Medical Devices Strategic Buyer	Brussels
27.	OCG	Director of Operations	Geneva
28.	OCG	Grant Manager	Geneva
29.	OCG	HCV referent	Geneva
30.	OCG	Myanmar Desk	Geneva
31.	OCG	Head of project Funding Interim & UNITAID Grant coordinator	Geneva
32.	OCG	Medical Coordinator	Maputo
33.	OCP	Medical Coordinator	Phnom Penh
34.	OCP	Head of Mission	Phnom Penh
35.	OCP	Cell manager, Papua New Guinea, Philippines, Cambodia, Russian Federation	Tokyo
36.	UNITAID pool	Grant Coordinator (former)	Geneva
37.	UNITAID pool	Grant Manager (former)	Geneva
38.	UNITAID pool	Financial Focal Point	Brussels

External

	Organisation	Position
1.	FIND	Head of Hepatitis C and HIV Programmes
2.	Coalition Plus	Senior Hepatitis Advocacy Manager
3.	UNITAID	Program Manager
4.	UNITAID	Technical officer
5.	Imperial College	Principal investigator
6.	University Bristol	Principal investigator
7.	University Bristol	Senior Research Associate in Mathematical Modelling and Health Economics

5.3 References

- CEPA (2018). *UNITAID End-of-Project Evaluation – MSF Grant on Implementation of CD4 and viral load testing in resource-limited settings.*
- Henze, N. (2015). *Evaluation of the added value, benefits, challenges and risks of the MSF - UNITAID collaboration.*
- UNITAID (2016). *Strategy 2017-2021.*
- WHO (2018). *Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection.*

Some 60 internal project documents were reviewed including:

- UNITAID (2015). *Grant Agreement and annexes*
- MSF (2015). *Intersectional agreement on the use of UNITAID Funding for HCV*
- MSF (2016). *Strategic Framework for HCV (draft).*
- MSF. *Annual reports on UNITAID Grant (HCV): 2015, 2016, 2017.*
- MedOps: summary of decisions related to UNITAID
- Minutes of HCV Contact Group: 2015-2018 (various)
- Correspondence to/from MSF UNITAID Pool (various)
- Presentations of MSF UNITAID Pool, AC and HCV Contact Group members (various)

5.4 Inception report

Capitalization: The MSF governance model of the UNITAID Grant “Ensuring access to the HCV treatment revolution for HCV/HIV co-infected patients in LMICs” Inception Report

14.07.2018 / TRAASS International

INTRODUCTION

1 Background and purpose of evaluation

Following the launch of DAAs, which revolutionary transformed the treatment and outcomes for the patients with HCV, in 2015 MSF set up screening and treatment of HCV in 8 sites in 7 countries, and carried out related operational research, legal and regulatory work as well as advocacy. This work was partially funded by UNITAID grant, amounted to USD13.3 (spent partially). The UNITAID funding for this project commenced in 2015, was limited to HCV treatment for HCV/HIV co-infected patients and ceased in June 2018.

The grant was led by OCG and implemented in collaboration between Epicentre, Access Campaign, OCB, OCP, OCA, MSF UK Imperial College and University of Bristol. The governance and management set-up was atypical for MSF.

The objective of this Capitalisation is to assess the advantages/disadvantages of the UNITAID grant governance and management model for:

- Project achievements, in terms of medical outcomes (i.e. MSF's capacity to screen and treat HCV for HCV/HIV co-infected patients in LMICs) and other results;
- Strategic decisions;
- The potential for replication in the future projects.

The purpose is to capitalise on the elements of the grant governance and management set up beneficial for project achievements, and to document lessons learnt and good practices of the collaboration between multiple MSF entities with a view to use elements of the set-up in future MSF interventions.

The time period covered in the Capitalisation is 2015-June 2018.

EVALUATION FRAMEWORK

2 Overview of the methodology and evaluation questions

The Capitalisation will be carried out through three main methods:

- a review of relevant documentation, including but not limited to project reports and minutes;
- semi-structured interviews and discussions with staff of VEU, OCG, Access Campaign, Epicentre, OCB, OCP, OCA, MSK UK Imperial College and University of Bristol, UNITAID; and
- placement of strategic decisions onto the project timeline and establishment of their causal link with the governance/management set-up and their influence on the outcomes.

The Capitalisation questions and sources/methods are detailed in the Evaluation matrix below.

2.1. Evaluation Matrix

Evaluations Questions	Sub-questions (not included in the ToR)	How is the judgement going to be formed?	Expected sources/methods
1. Overview of the main achievements of the project foreseen within the grant and beyond the grant (creation of interest in the neglected topic, access to treatment beyond the UNITAID grant, collaboration and research ambitions and achievements, etc.)	<i>1a. Where were the main achievements (such as input into WHO guideline, change in Policies, management of patients and influence of the model of care, etc.)</i>	<p>Identification of the project achievements in the categories:</p> <ul style="list-style-type: none"> - Medical outcomes (patients treated, activities completed, etc); - Advocacy; - Operational research ambitions and achievements; - Legal and regulatory work. <p>Assessment of the results in comparison to the project goals/indicators, review of the activity progress reports in the annual reports, discussion of the project expectations vs achievements.</p>	<ul style="list-style-type: none"> - Document Review - Interviews
2. Which elements of the grant governance and management set up created for this project (within and across OCs, collaboration with Epicentre and Access campaign, Universities, UNITAID) were beneficial/harmful for the achievements of the results?	<p><i>2a. What is the strategic advantage of this partnerships and how did it help MSF to open the market of HCV and then to enlarge it?</i></p> <p><i>2b. What is the right set-up and was it the most reliable?</i></p>	<p>Identification of the grant governance and management setup. The following elements are to be examined:</p> <ul style="list-style-type: none"> - Alignment of strategic vision, goals, etc between UNITAID and MSF and how it influenced the results; - Decision making process, including participativeness, transparency and timeliness aspects; - Reporting system; - Roles and Responsibilities in terms of operational and strategic management set-up and catalytic (or inhibitive) role of the collaboration. <p>Assessment of contribution of the above elements to achievement of the project results.</p>	<ul style="list-style-type: none"> - Document Review - Interviews
<p>3. Which strategic decisions were made in key phases in the project's lifetime?</p> <p>a. In which context were these decisions been taken and what were the reasons for these decisions?</p>	<i>3c. Clarification: the task is to explore the casual links between the governance set-up and strategic decisions, including their timeliness, and the eventual outcome it brought.</i>	<p>Identification of decisions regarded as strategic and placement of them onto the project timeline.</p> <p>Establishment of the role of these decisions for the project results, documenting the context and reasoning behind the decisions for lessons learned purpose of the capitalisation.</p>	<ul style="list-style-type: none"> - Document Review - Interviews

b. To what degree were these decisions beneficial to the project's overall objective and integration of the project into related MSF activities?			
4. What is the catalytic role of the grant on the project achievements?	<i>4a. What is the added value of UNITAID grant for MSF?</i>	Discussion with the key stakeholders on the grant role for different aspects of the project.	- Document Review - Interviews
5. What is the potential of this atypical governance and management set up to be used in future MSF interventions?	<i>5a. Did MSF need such a grant to do similar work in the future?</i> <i>5b. Is it a model to replicate for a collaboration within and across OCs? If yes, in which context/circumstances and which elements.</i>	Identification of the successful elements of the grant management/governance setup and of the context essential for the use of those elements in the future projects.	- Document Review - Interviews

3 Limitations

The following limitations have been identified with accompanying mitigation strategies to minimise their impact:

- The period of the data collection falls in July/August, so availability of the stakeholders in the OCs, Epicentre, Access campaign, Universities, and UNITAID is limited due to holidays, thus limiting the overall reach of the key informants.
Mitigation strategy: Interviews will be requested with a broad range of stakeholders and management to cover all opinions.
- As a part of Capitalisation, causal links between governance set-up, strategic decisions made, and project achievements will need to be established. This requires professional judgement and involves potential biases.
Mitigation strategy: The causality will be challenged during the interviews, and more than a single informant will need to express similar opinion to verify the causal links. Interviews with the key informants will be held by more than one consultant so the judgements will be formed by multiple consultants and will be peer reviewed.
- The UNITAID Grant covered a broad range of activities implemented by at least eight MSF entities/partners. Information on the implementation and consequent achievements may therefore be spread across these entities/partners and could be difficult to access.
Mitigation strategy: Contact will be established with all known participating MSF entities/partners. Further, a snowballing sampling approach will be adopted (i.e. asking interviewees of other potential interviewees) to ensure that the maximum number of stakeholders are reached.

EVALUATION METHODOLOGY

4 Key informants and how they will be involved?

Key informant person/groups	Proposed means of involvement	Outline issues to be explored
MSF OCs (OCG, OCA, OCB, OCP)	Face-to-face interviews Skype interviews	All questions (above)

APU	Skype interviews	All questions (above)
CAME	Skype interviews	All questions (above)
DNDi	Skype interviews	All questions (above)
Epicentre	Skype interviews	All questions (above)
Imperial College	Skype interviews	All questions (above)
University Bristol	Skype interviews	All questions (above)
MSF Supply	Skype interviews	All questions (above)
MSF UK - Manson Unit	Skype interviews	All questions (above)
UNITAID	Face-to-face interviews	All questions (above)

5 Key documents to be reviewed

- UNITAID Annual Reports
- SEU Evaluation Report, 2015
- Minutes of UNITAID-MSF meetings
- Minutes of HCV contact group meetings
- Agreements between the different partners – Intersection Agreement
- WHO Unitaids HCV Partners' Meeting Reports
- Emails/Letters exchanged
- Logframes and indicators documents
- UNITAID Strategy 2017-2021 report
- MSF Viral Hepatitis Extended Group meeting reports
- ...

6 Interviews/other data-collection methods (e.g. survey, etc)

- A review of all the available documentation on the grant and project will be made.
 - Semi-structured interviews will be held with all key informants.
- Please also refer to the methodology overview in p.2 above.

7 Field visit (if applicable)

No field visit is required for this Capitalisation.

WORK PLAN

8 Timeline

Tasks	June, July						August				No days
	25	2	9	16	23	30	6	13	20	27	
1. Inception											
Documents review/analysis											2
Briefing at VEU + first round of Interviews (Skype)											1
Inception Report (IR)											1
Feedback and adjustment - IR											1
2. Data collection											
Interviews in Geneva - OCG											1
Interviews with other OCGs (incl. travel if needed)											1
Interviews with EPICENTRE, Access Campaign, MSF UK Imperial College, University of Bristol and UNITAID (off-site)											4
Debriefing with VEU (Skype) and OCG											1
3. Analysis and Reporting											
Data analysis - Preliminary findings - Draft report											5
Submission of Draft Report											-
Feedback on Draft Report											-
Development and submission of the Final Report											1
Presentations (incl. travel)											2
Total											20

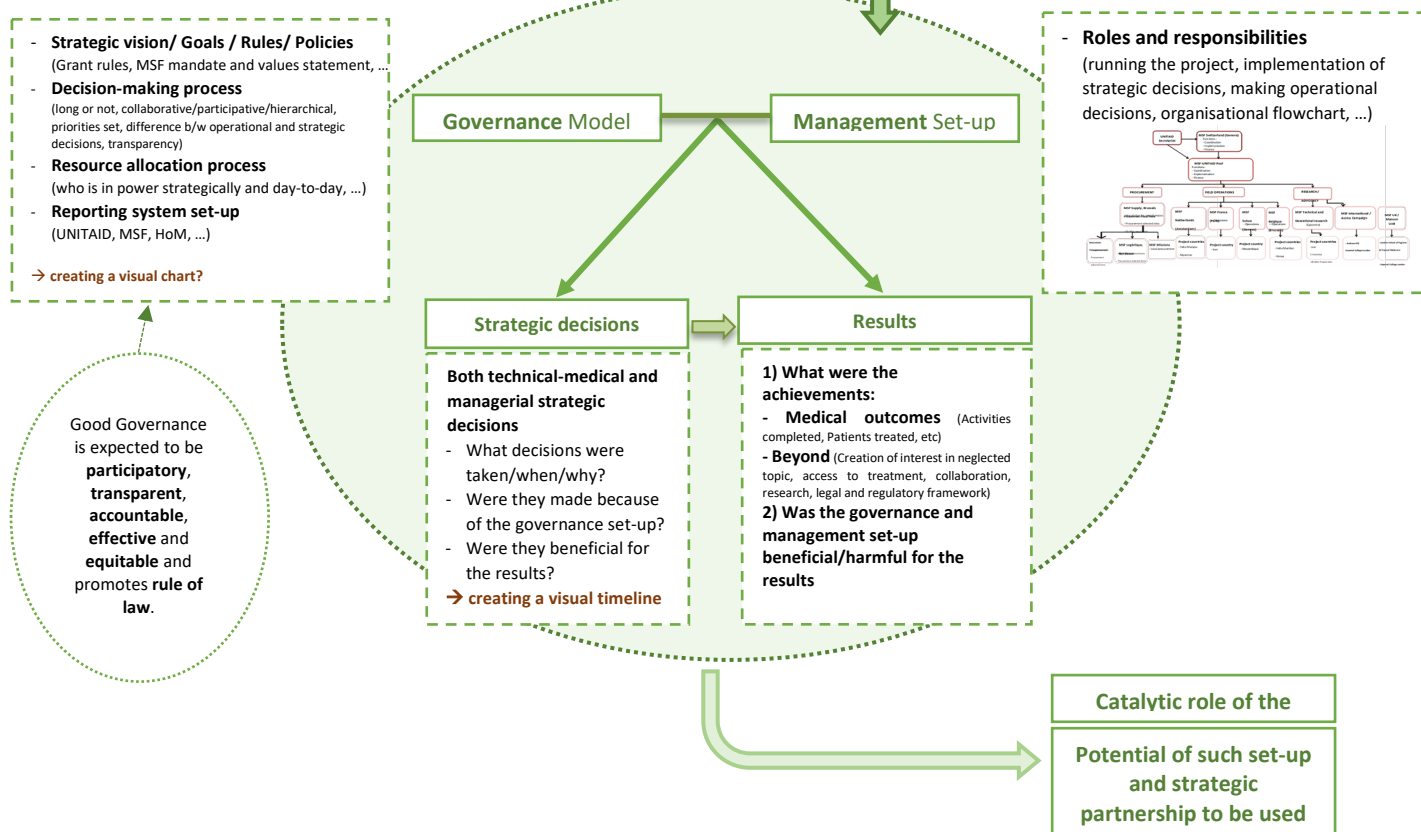
9 Structure of the final report of the evaluation (review and / or complete)

Table of contents
Abbreviations
Executive summary and main recommendations
Introduction
Background
Purpose and objectives of the evaluation
Methodology
Limitations
Findings
a)
b)
...
Discussion and conclusions
...
Recommendations/Lessons learned
a)
b)
...
Annexes

Below is the visual overview of the Capitalisation objectives and the main elements of the governance and management setup, which are to be assessed.

TRAASS International is to...

Capitalise on the ...



5.5 Terms of reference

TERMS OF REFERENCE

FOR

Capitalization: The MSF governance model of the UNITAID Grant “Ensuring access to the HCV treatment revolution for HCV/HIV co-infected patients in LMICs”	
Date:	22.06.2018
Commissioned by	Grant Leader
Commissioner as of 25.6.2018	Operational Director OCG
Duration of evaluation	14.6.-15.9.2018
Time period that is evaluated	Total duration of the project: 2015-2018 (3,5 years)
ToR elaborated by	Grant Leader and VEU

Capitalization commissioned to: VEU

1. CONTEXT

In 2015, MSF received a grant valued at USD 13.3 million from UNITAID to implement a 3 years project "Ensuring access to the HCV treatment revolution for HCV/HIV co-infected patients in LMICs". This grant has been recently extended to June 2018.

The grant is led by OCG and implemented in collaboration between Epicentre, Access Campaign, OCB, OCP, OCA, MSF UK Imperial College and University of Bristol.

In 2013, the launch of direct acting antivirals (DAAs) which can cure Hepatitis C virus (HCV) within three months has created great opportunities for solving a pressing global public health issue once and for all. Inspired by the potential of the highly effective drugs and outraged by scandalously high prices that originator companies have set for the products, many actors (governments, international bodies and aid agencies, civil society, researchers, drug companies, funders) including MSF have started to engage on the HCV issue.

Since Médecins Sans Frontières (MSF) provides care to several tens of thousands of HIV patients worldwide, the organization immediately acknowledged the importance of treating HCV in this particularly vulnerable group: Co- infection of HIV and HCV doubles the risk of mother-to-child transmission of HCV, is associated with less spontaneous HCV clearance, higher HCV viral loads, and more rapid progression of liver disease. In the framework of the UNITAID grant, since 2015, MSF has set up screening and treatment of HCV in 8 sites in 7 countries, and carried out related operational research, legal and regulatory work as well as advocacy.

2. OVERALL OBJECTIVE and PURPOSE

OVERALL OBJECTIVE:

To assess the advantages/disadvantages of the UNITAID grant governance and management model for:

- Project achievements, in terms of medical outcomes (i.e. MSF's capacity to screen and treat HCV for HCV/ HIV co-infected patients in LMICs) and beyond;
- Strategic decisions;
- The potential for replication in the future projects.

PURPOSE:

- To capitalize the main achievements of the project (related both to medical outcomes foreseen in the UNITAID grant and also to triggering an interest within MSF and beyond in a highly neglected medical topic)
- To document lessons learnt and good practices of the collaboration between multiple MSF entities (4 OCs, EPICENTRE, Access Campaign), MSF UK Imperial College, University of Bristol and UNITAID
- To leverage the learnings from the HCV treatment for HCV/HIV co-infected in future MSF projects

3. KEY EVALUATION QUESTIONS

1. Overview of the main achievements of the project (foreseen within the grant (activities completed, patients treated, etc.) and beyond the grant (creation of interest in the neglected topic, access to treatment beyond the UNITAID grant, collaboration and research ambitions and achievements, etc.)
2. Which features of the grant governance and management set up¹ created for this project (within and across OCs, collaboration with Epicentre and Access campaign, Universities, UNITAID) were beneficial/ harmful for the achievements of the results?
3. Which strategic decisions were made in key phases in the project's lifetime²?
 - a. In which context were these decisions been taken and what were the reasons for these decisions?
 - b. To what degree were these decisions beneficial to the project's overall objective and integration of the project into related MSF activities?
4. What is the catalytic role of the grant on the project achievements?
5. What is the potential of this atypical governance and management set up to be used in future MSF interventions?

4. EXPECTED RESULTS and INTENDED USE OF THE EVALUATION

Outputs:

- Draft report outlining the main achievements of the grant and the advantages and disadvantages of the project for

¹ Management setup in this context is understood as interplay between the organigram, internal reporting procedures and reporting structures and decision making

² In project design phase, inception phase, implementation phase, project closing

- a) The governance model and the management set up created for the UNITAID grant
 - b) MSF's capacity to treat HCV for HCV/HIV co-infected patients in LMICs
 - Final Report
 - Presentations:
 - Preliminary presentation
 - Final presentation in OCG
 - Other relevant platforms
1. Medical departments to develop appropriate tools for future work on the topic
 2. OCs to reflect on further replication of beneficial structures

5. PRACTICAL IMPLEMENTATION OF THE EVALUATION

Number of evaluators	1
Timing of the evaluation	June- August 2018

Tasks	# of days - Evaluator	Deliverables
For preparation, document review, first interviews and inception report	5	Inception report
For interviews in 2 Ocs (incl. Travel) and from off-site	7	
Data analysis, report writing, integration of feedback and preparation of presentations	6	Final report
For presentations (incl. travel)	2	Presentations
Total	20	

6. TOOLS AND METHODOLOGY PROPOSED (if any)

- Review and analysis of project documents and relevant medical documents
- Key informant interviews
- Establishment of timelines on key decisions and contextual factors
- Visualization of organizational structures
- Observations
- Quantitative and qualitative data gathering and analysis

7. DOCUMENTATION FOR READING

Project Documents (Annual reports, LogFrame etc.)

Henze, N. (2015). Evaluation of the added value, benefits, challenges and risks of the MSF - UNITAID collaboration

CEPA (2018). Unitaid End-of-Project Evaluation – MSF Grant on Implementation of CD4 and Viral Load Testing in Resource-Limited Settings
Other documents will be shared in the inception phase.

8. STAKEHOLDERS AND INTERVIEWEES

- Interviews with key informants at OC and field levels
- Interviews with key informants in Epicentre, UNITAID and Access Campaign
- Interviews with relevant implementing staff in Missions

9. JOB PROFILE/S of EVALUATOR/S

Mandatory:

- Relevant academic background
- Extensive evaluation experience in humanitarian approaches and programs
- Proven experience in analysis of organizational governance structures
- Solid experience in data collection methodology and analysis of qualitative data
- Strong communication skills
- Ability to discuss complex issues in a clear and concise way (ideally through visualization

techniques) Desirable:

- Experience working with MSF
- Sound understanding of the medical topic
- Strong facilitation skills