MEDECINS SANS FRONTIERES
LÄKARE UTAN GRÄNSER

MSF SWEDEN INNOVATION UNIT

PROJECT REPORT

— Smart Time Temperature Indicator

This report details the product and process of an innovative collaboration between Médecins Sans Frontières and external partners, focussed on the creation of a printed electronic indicator for use in the humanitarian cold chain.

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INTRODUCTION

The cold chain is a key process in many medical, humanitarian, organisations. It encompasses the transport, handling and storage of temperature sensitive pharmaceuticals (medicines, vaccines and lab-tests) in their journey from manufacturer to medical facility. These pharmaceuticals have to be kept within a certain temperature range (often between 2 and 8°C) to ensure their quality, efficiency and safety. What temperatures an item can survive, and for how long, depends on the product: some are more heat- or freeze-stable than others.

Despite several measures, including the development of protocols on handling and using time-temperature indicators, humanitarian organisations continue to encounter difficulties with the proper monitoring of cold chain items.

This results in uncertain quality of items at the point of use, which is why MSF's Operational Centre Amsterdam (OCA) asked the Swedish Innovation Unit (SIU) to identify new tools that could provide a better indication of the quality of items throughout the complete cold chain process. Although this project was initiated and carried out by OCA, many of the challenges are also encountered by other OCs, and NGOs.

LogTag — Electronic time-temperature logger that measures on box- or fridge-level and can be readout for detailed information

FreezeTag — Electronic freeze-alert that measures on box- or fridge-level and changes status when below 0°C for more than one hour

3M card — Heat exposure monitoring strip that measures heat accumulation on box- or fridge-level, and colours windows blue accordingly

Vaccine Vial Monitor — Vaccine monitor that measures heat accumulation for individual vaccines, and changes colour accordingly

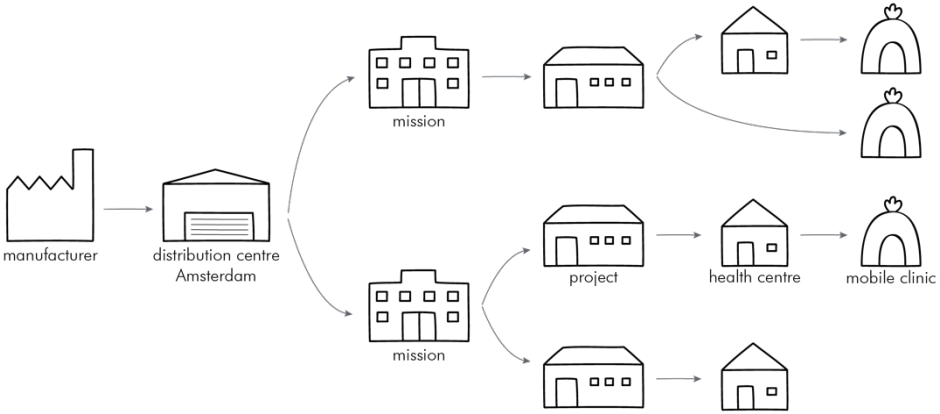
An overview of the monitors that are currently used in the OCA cold chain processes.

In the **initiation** phase of this project, needs were analysed and a thorough exploration of existing solutions was conducted. It quickly became clear that existing tools did not meet OCA's needs, and that additional expertise was needed, so the SIU engaged a number of external actors in the development of a new time-temperature indicator based on printed electronics.

The **development** phase utilised a user-centered design approach for a more in-depth analysis of needs and wishes of OCA (field) staff, whilst also starting an external collaboration for the production of working prototypes of a possible solution. This phase concluded with a field study with working prototypes in MSF's Bangladesh mission.

The next step in this project is to improve reliability and explore mass production options. For this, MSF will not be as involved as in previous phases, but will stay involved as an advisor to ensure the humanitarian needs are met.

The aim of this project was, and is, to catalyse change in how the cold chain is monitored. It is therefore hopeful that it results in the **implementation** of a new cold chain monitor that meets MSF's needs.



In their journey, cold chain items will pass various locations. Items that start at the same location will not necessarily end up at the same location.

1. THE INNOVATION PROCESS

The MSF Sweden Innovation Unit uses a three-phase innovation process of initiation, development and implementation. Although these phases principally follow each other, they also often overlap, as was the case in this project.

Many innovation processes are conducted collaboratively. This is done to balance desirability, viability and feasibility, which increases the value of the design solution, as it will be:

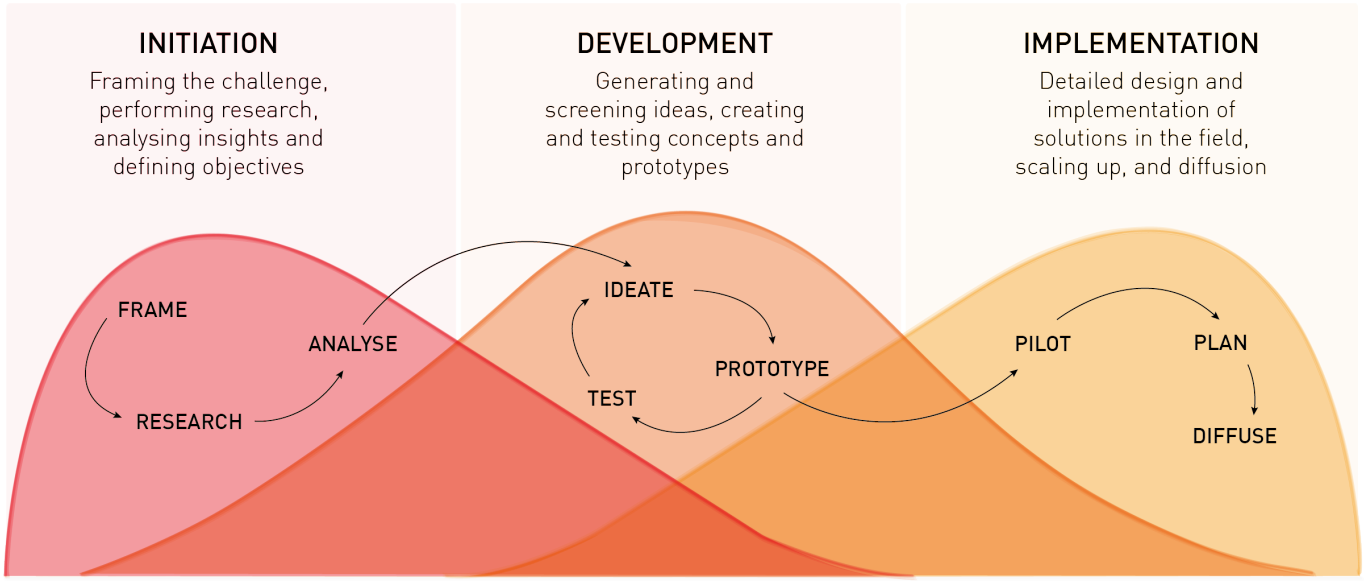
- a desirable solution the user really needs.
- a feasible solution that is (technically) possible.
- a profitable solution with a sustainable business model.

This is one of the reasons why the SIU operates on a collaborative and open basis. They believe that external actors have value to add through their expertise and aim to harness this added value throughout the design process.

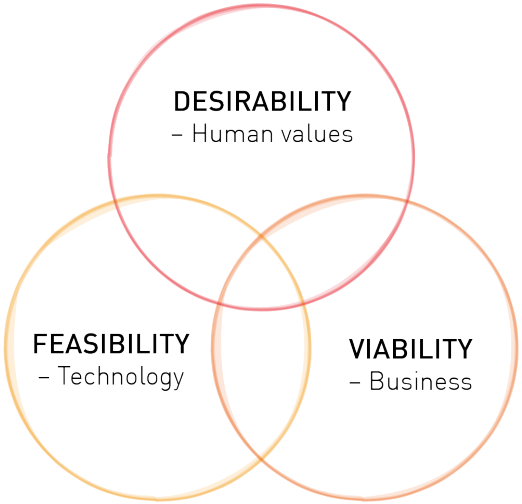
In this project, the three main partners involved, all brought a clear benefit to the project: MSF brought the needs; academia brought the technology; and business brought the viability of bringing the result to market.

MSF can play an important role in the development of new products, because:

- they represent the humanitarian sector by providing the needs and an advocacy platform.
- they provide expertise from the humanitarian perspective, which is very valuable to companies developing products for the sector.
- by being involved at the early stage of development, MSF can ensure new products are designed with their processes in mind.



The three-phase innovation process MSF SIU uses is not a linear process, but requires iterations to improve the design solution to make it fit perfectly the situation in which it has to be used.



Finding the balance between those three criteria will increase the value of the design solution.

2. USER-CENTERED DESIGN APPROACH

While Acreo and Beneli focused on the technical development and transfer of technical knowledge in this project, MSF focussed on the requirements for user-interaction in the MSF field context. As OCA had limited expertise in this, the SIU and students from the TU Delft (a technical university in the Netherlands; faculty of Industrial Design Engineering) took this on.

The user-centered design approach used in this project takes needs and requirements from the potential users by involving them directly in the design process. In doing this, the product is more likely to fit the needs and wishes of the end-users and the processes within which it has to work. Moreover, this approach allows the users — or in this case MSF staff — to understand the basis on which changes are made, and it gives them the opportunity to play an important role in shaping them.

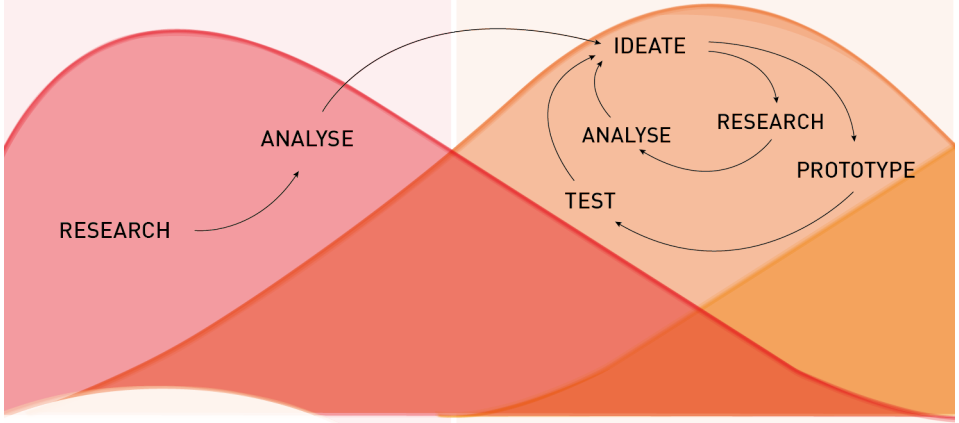
It is also important to highlight that an innovation process is not a linear one, but one that requires iterations in which steps are repeated to improve the product.

Taking into account MSF's needs, wishes and perspective throughout the development process meant not only involving MSF office staff, but also asking field staff for input and feedback, as they will ultimately have to work with the solution produced and integrate it in to their current processes. Hence, an important aspect of this project was field testing prototypes in an MSF mission and collecting feedback from staff coming back from the field.

In the user-centered design approach the focus during the entire innovation process is on the user and the context in which he has to work:

While in the **initiation phase** users will be involved to give insights in the current situation, to share their perspective and to express their needs and wishes;

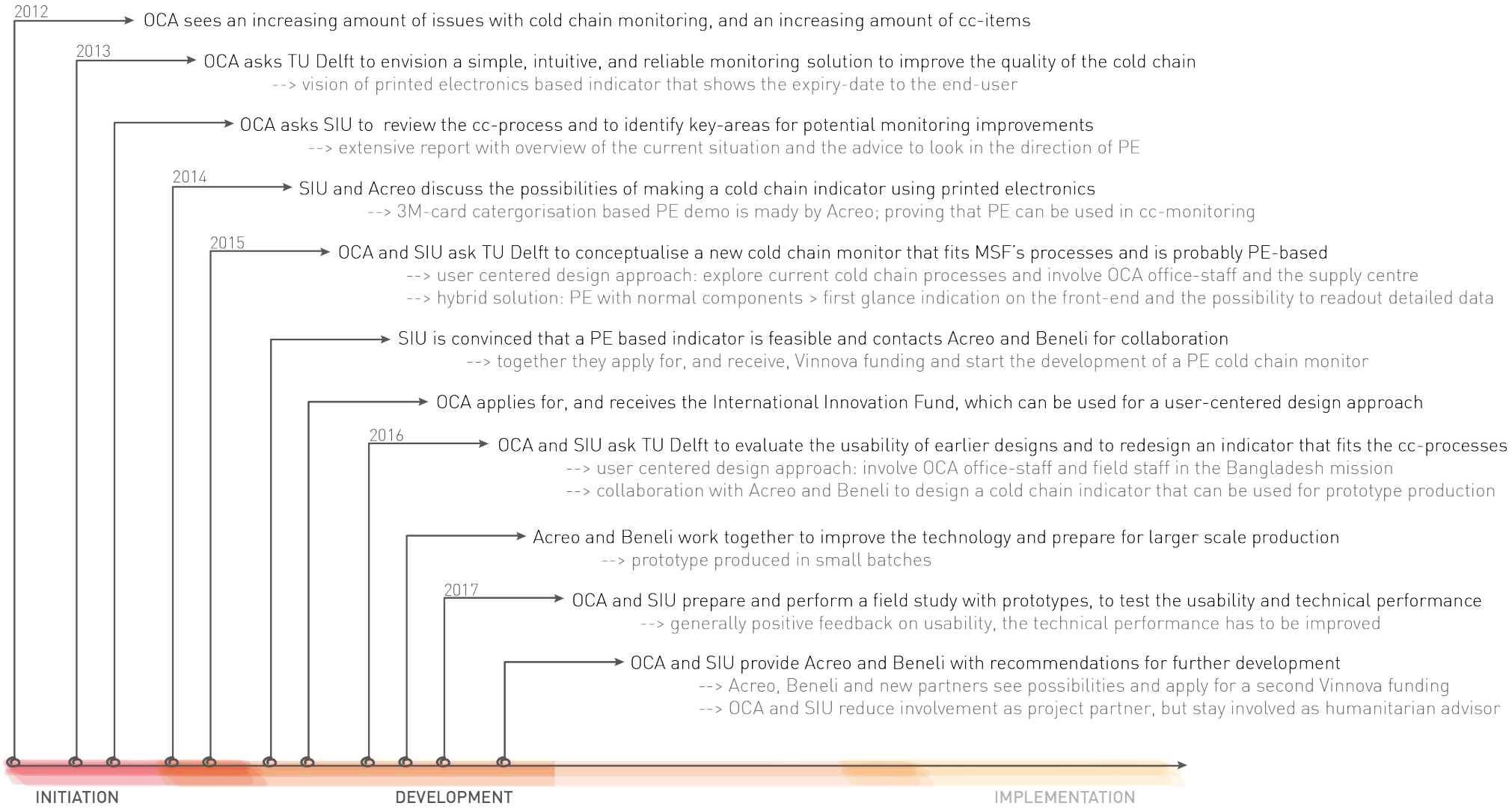
In the **development phase** users are asked to give feedback on the initial designs and to indicate what works for them and what does not.



During an innovation project it is important not only to look at the development of the product, but to also keep in mind that it has to be positioned in current – or new – processes.
That is why during the development phase you continue to research and analyse to get more insights in the situation the product has to fit.

In the development phase the design of the indicator was tested in the field. This was done to be able to balance the usability preferences as expressed by MSF (field) staff with the technical possibilities.

3. PROJECT TIMELINE



4. INITIATION PHASE

In 2014, OCA spent €4.2 million on 180 different thermo-sensitive items (laboratory products, vaccinations and drugs). This represents 10% of the total Amsterdam Procurement Unit budget. The use of cold chain items (specifically laboratory products) is still growing, leading to drastically increasing medical and logistical challenges to monitor the quality of cold chain items. This increase is not only seen in MSF, but is taking place in resource-constrained cold supply chains across the world.

MSF is already engaging in different strategies to address these challenges: advocating for thermo-stable products; improving cold transport boxes; improving awareness and training in the field; shortening travel times; and enhancing transport processes.

In addition OCA decided to look at the gap in the quality monitoring of cold chain items, which is a complex process.

This is mainly because MSF is:

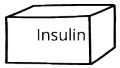
- working with people from all over the world
- monitoring many small steps of the journey
- working in many different situations
- data has to be combined before making a decision

Which leads to:

- unnecessary destruction of cold chain items
- intensive email exchange between field and hq
- uncertain quality
- increasing requests for training and improvement

At the request of OCA, the TU Delft and SIU started exploring opportunities for a new cold chain monitor. This exploration encompassed a comprehensive landscape analysis looking at various types of solutions and resulted in their recommendation to look at printed electronics as a possible opportunity.

To explore the possibilities of this technology, a student-team from the TU Delft was asked to design an indicator for MSF. They analysed MSF's cold chain processes and the possibilities printed electronics could offer, and concluded that this technology had the potential to address the gaps in quality control of the MSF cold chain because:



It allows for monitoring on secondary packaging level

Specific time-temperature ranges could be used

The status of a cold chain item is directly visible to the end-user

It is easy to collect detailed data for quick decision making

It is expected to become a reliable and precise technology

It will be cost effective (compared to the current financial impact of problems) — aiming for a cost price of less than a dollar

5. COLLABORATION

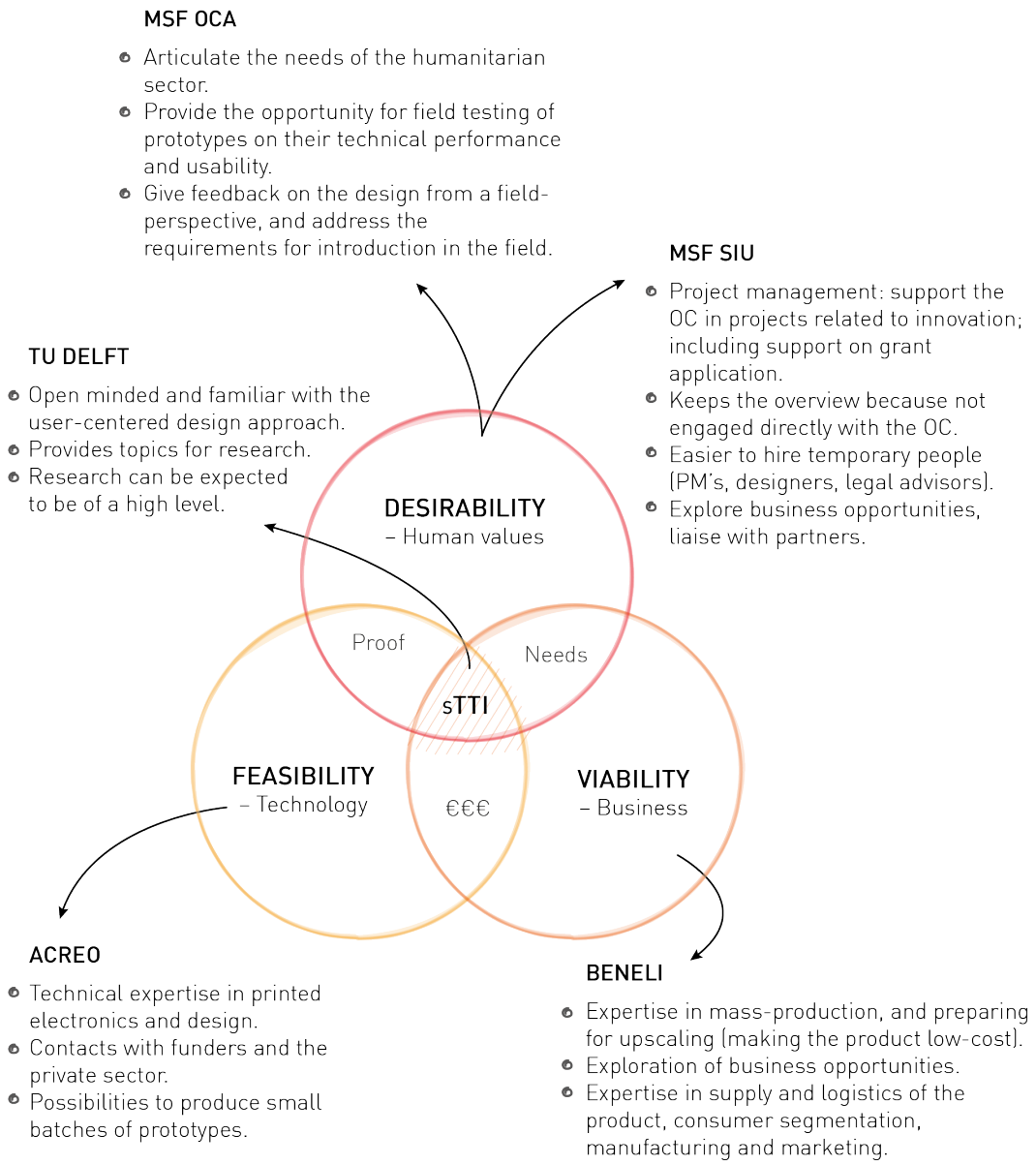
From the in-depth mapping of existing cold chain monitors, it was clear that MSF could not find an indicator that fulfilled their needs, yet it was also clear that MSF could not develop a market-level indicator on their own. Collaborating with other parties who could help bridging this gap in expertise was therefore essential when designing a new indicator to properly fit MSF operational needs.

Entering into an external partnership at such an early stage was not without its risk as: it was not clear if the final product would be robust enough for MSF's settings; it was difficult to predict how fast the printed electronics technology would develop; and it was by no means confirmed that the product would be commercially viable.

However, alternatives were expected to be absent for years to come and the opportunity to catalyse change was seen to outweighed the risks. Therefore a formal partnership was formed with Acreo (a Swedish research institute specialising in printed electronics) and Beneli (a Swedish printing company looking to expand into printed electronics). Together, a successful three-way application was made to the Swedish Vinnova fund, in which the goals were to:

- Create smart label indicators to show it was technically possible.
- Transfer competency within printed electronics from Acreo to Beneli.
- Produce functioning prototypes for field tests.
- Perform field-tests on usability and technical feasibility.

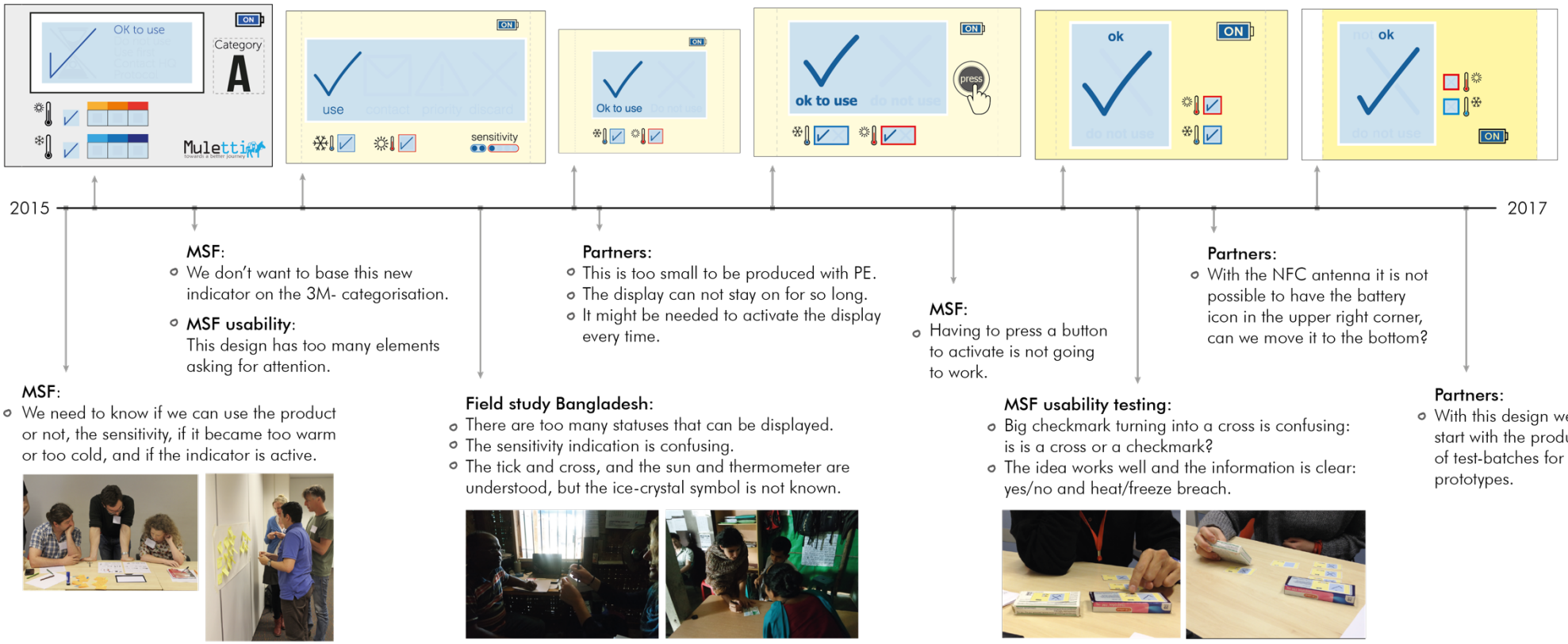
The focus in the Vinnova project was on the technical development and performance of the new indicator, but it did not emphasise the challenges regarding its usability. As this was one of the most important factors for MSF to make the indicator in to a success, the decision was made to apply internally for International Innovation Fund money — which was also successful.



6. DEVELOPMENT OF THE INDICATOR

An important aspect in the development of the indicator was to find solutions for the conflicts that arose between usability preferences and technical possibilities. It therefore was not only important to receive input on the design from MSF (field) staff, but also to work in close collaboration with the partners.

During this process MSF, Acreo and Beneli challenged each other with new ideas, requirements and limitations. While MSF had to change the design of the indicator because of technical limitations, the partners were asked to explore new technical layouts, and to develop the technology in other directions than they might have chosen themselves.

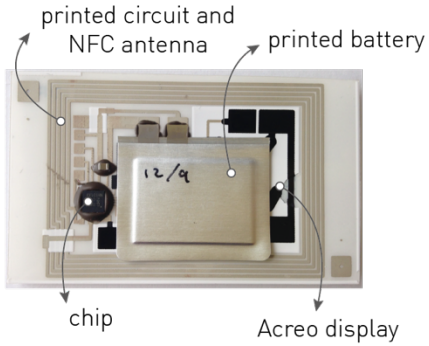


Apart from the designs displayed in this timeline many more layouts were tried and tested, but rejected for several reasons.

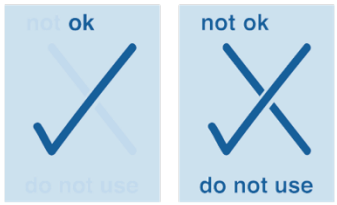
7. THE INDICATOR

The new monitor is a digital time-temperature indicator that can be placed on secondary packages of temperature sensitive pharmaceuticals. It allows for monitoring of the entire journey a product makes: from warehouse to medical facility in the field. The indicator is made with printed electronics, which is a relatively young technology that offers the opportunity to add electronic or bio-electronic function to, for example, paper and plastic products. The major advantages of this technology are: high efficiency of material use, increasing environmental credentials, relatively low costs and a minimal thickness compared to conventional electronics.

Most of the indicator's elements can be made with printed electronics. Only the chip is not printed, but can be mounted on the printed circuit.



The indicator senses both heat and freezing temperatures and responds when measured temperatures exceed the programmed acceptable range. When this happens, the status on the display — where most important information is given to the end-user — will change from 'ok' to 'not ok'.



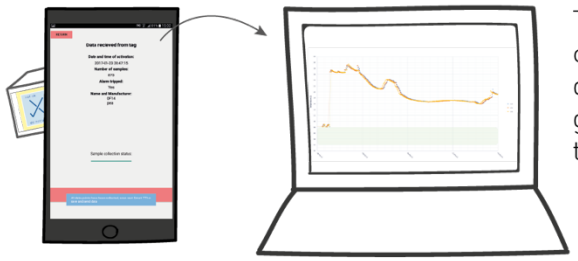
In case the indicator shows 'not ok', it also informs users on the reason for the breach:

the item has become too warm

the item has become too cold

Sticky tabs allow for easy attachment of the indicator to cold chain packages.

With an NFC enabled device (e.g. tablet or smartphone) detailed time-temperature information can be readout from the indicator.



The pharmacist can review this data and quickly give feedback to the field.

The Acreo display is an electrochromic display that can be made with regular screen-printing processes using a proprietary conductive ink. The display is cheap, ultrathin, biodegradable and could be printed directly on the surface of a package. Printed displays require a very low voltage and they are flexible and robust.

The indicator's chip can be programmed with product specific time-temperature data; this is important as not all cold chain products can resist the same temperatures over time.

The chip contains a temperature sensor, memory and a NFC-component, which allows for communication between the indicator and a NFC enabled device.

8. FIELD TESTING

In February 2017 a field test took place in the MSF OCA's Bangladesh mission. The main objective of this study was to test functional prototypes of the indicator in realistic settings for their robustness, performance and usability.

To test the technical performance, a shipment test was setup, indicators were stored in and outside fridges and readout regularly, and a climate chamber test was performed to compare the performance of the indicators to LogTags, 3M-cards and Freezetags. For usability testing, simulation sessions with field staff were organised. In those sessions feedback was collected from both the logistics and medical department and from both expats and national staff.

In general field staff were positive about the indicator and believed that it could help guarantee the quality of used cold chain items. Field staff were also positive about the indicator providing clear and direct information about the status of a specific product.

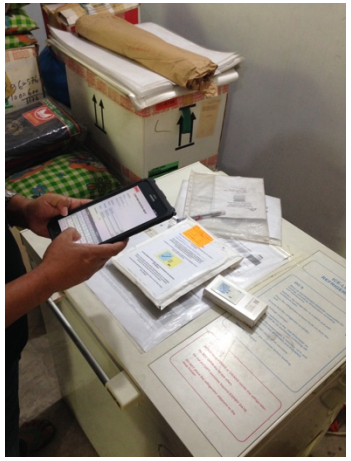
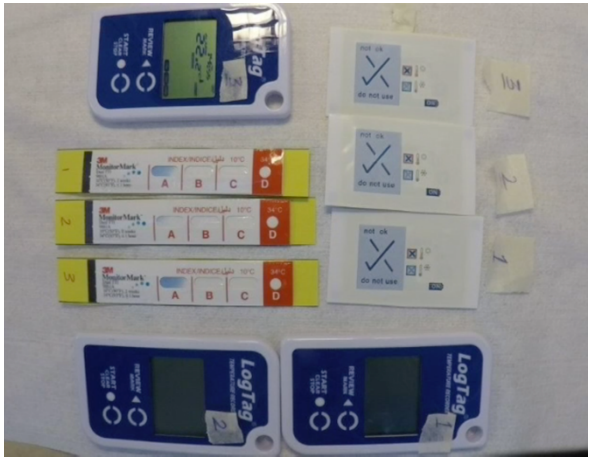
That said, concern was expressed on some points — such as waterproofing and the efficiency of checking each indicator.

Regarding the technical performance of the indicators the outcomes were largely positive: graphic readouts of the indicator data showed close lines to that of the LogTags, and in the climate chamber test the indicators responded at the same times as the LogTags, and in a timeframe close to the 3M-cards.

In the shipment test the importance of secondary package monitoring became clear, as a difference between the LogTag data from different places in the shipment-box was seen. Moreover, in this case the prototypes displayed a cold chain breach, while this was not noticed with the other monitors or hand-made notes.

Despite these positive outcomes, it was also seen that the prototypes are, at this stage of development, not yet robust enough for the field, as only 14 out of 80 indicators (17,5%) worked without a single technical issues for the complete six-week testing period. The issues encountered (including connectivity, hardware and software problems) will need to be solved, but shown not to be seen as a big obstacle and are expected to be tackled in a next phase of development.



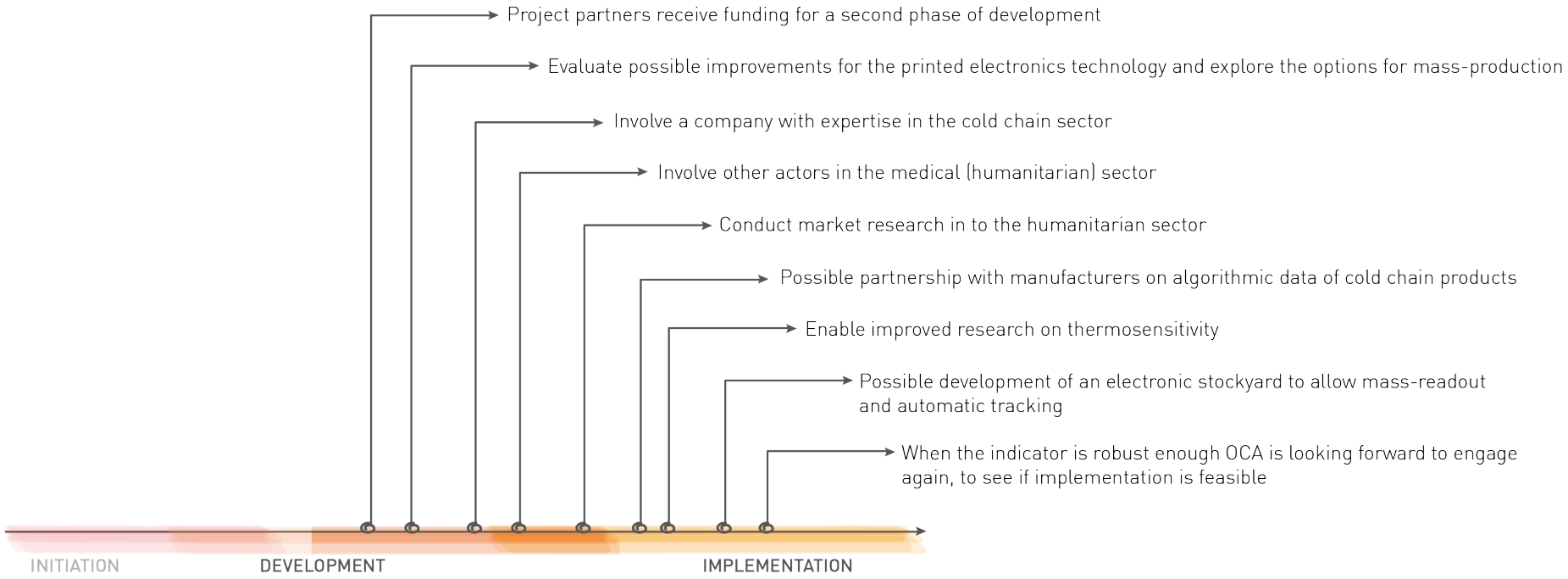
From left to right: a simulation session with field staff from the logistics team; a simulation session with a pharmacist; reading out of the 'shipment test indicators' by the SupplyLog; and a still from the climate chamber test.

9. NEXT STEPS

This project was ambitious in scope and objective. However, at the end of the first phase, the project has exceeded our expectations. The technology incorporated into the indicator is far more advanced than at the point the project was initiated and the indicator is now attracting interest from various commercial actors.

Field testing the prototype gave two main insights: that the indicator clearly has potential; and that the reliability needs to be improved. To address these, an expanded consortium — now including a partner with experience in manufacturing and bringing cold chain indicators to market — has applied for further funding to take this prototype to mass production.

For MSF, involvement in the project will decrease, but remain as an advocacy component through the SIU. The reason for this is that we feel like the groundwork for a successful product — which can fit the MSF brief — has been laid, and now the question becomes at what point the indicator can reach the reliability standards to appear on the market and be considered as a really possibility for use. This redefined partnership will allow for commercial interests to drive the project forward to market.



10. INSIGHTS IN THE MSF COLD CHAIN

While developing the new indicator, new insights and discoveries were made in to the existing products and processes contained within the OCA cold chain. Here are some of the most interesting and valuable insights that came up during the project.

THE COMPLEXITY OF MONITORING THE MSF COLD CHAIN

The current monitoring systems of OCA's cold chain is more complex than many people might think. This is because of:

- The use of unintuitive cold chain monitors that do not provide information about a specific product, but about a volume of cold chain items.
- The information from different indicators has to be combined before a decision can be made about the quality of a specific item.
- Cultural, educational, and situational differences make that it is difficult for field staff to work according to generic protocols.

With the new indicator field staff is given information about individual products with clear and unambiguous information.

VARIATIONS IN COLD CHAIN MONITORING

The testing of the prototype indicator confirmed that the existing system allows for relatively large variations between existing monitors. In climate chamber tests, the prototype was seen to be more sensitive than the 3M card and FreezeTag.
Additionally, a number of prototypes which were used in the shipment test displayed a cold chain breach upon arrival, whereas traditional indicators and manual notes used for the tertiary packaging did not, showing the value of monitoring the complete cold chain at the secondary packaging level.

THE MISSING 29 MINUTES

One of the main monitors used in the current system is the LogTag, which measures temperatures every 15 minutes as standard. When a temperature above 8°C or below 2°C is measured more than four times, it will give an alarm. However, this system allows for up to 29 minutes of an excursion to go unnoticed if there are consecutive high temperatures recorded, or missed entirely if the excursion is under 15 minutes.

The new indicator can potentially address this issue, as it is possible to program it to start measuring more frequently at the moment it measures a temperature near to the limits of the safe range.

UNVERIFIED TEMPERATURE LIMITS

In the project it became very clear that MSF has very little accurate thermos-sensitivity data from manufacturers. The current categorisation system is out-dated and is difficult to stick to because products have increasingly varied sensitivity profiles.
With the new indicator, it might be more attractive for manufacturers to provide more detailed time-temperature data to be programmed on the indicators.

11. LESSONS LEARNED

Involvement in this project led to various insights on the role MSF OCA could play as a partner in innovation projects, the challenges this brings and how MSF OCA could deal with this in future projects.

MSF as a partner in the product development process

MSF can act as a catalyser in the development of products that can change the way medical assistance can be provided in resource-constrained settings worldwide. By being involved in the development of a product in an early stage MSF can help to properly frame the needs discussion. What is needed for this is open-mindedness, support from the different layers within the organisation, and the opportunity to try new things without having to know what the exact result will be.

Using a triangular partnership model — which incorporates academia and business — is the ideal structure for innovation, research and development, and is a great way to overcome the often contextual mismatch of products designed for the humanitarian space. MSF's expertise is highly valuable to external actors and these kind of projects allow OCA to potentially leverage value for the good of the movement.

Challenges for MSF OCA

An innovation process can be a long one, and it is important to learn to balance operational needs — which often require direct action — with realistic expectations for a development process. Although not always successful, the innovation process can deliver sustainable long-term solutions that address the root cause of the issue, as well as the immediate problem.

What MSF OCA could learn about innovation projects

It should be defined within the organisation what the criteria are for starting an innovation project, and how this can be taken into account when internal agreements are made on setting priorities.

Before starting an innovation project (especially when funded with external money or when external partners are involved), roles and responsibilities between the different stakeholders need to be well defined. The SIU can help OCs in doing this.

An important part of an innovation project is to fully map the roles of different departments in relation to the subject, to ensure all stakeholders are involved in the development process and are not unintentionally left out.

When entering into projects in collaboration with external partners — with the aim of creating a commercially attractive product — it is important for MSF to be aware of the commitment to partners and responsibilities the responsibilities this brings. Also, it is important to plan in terms of licensing, patents and IP options available.

There potentially becomes a tipping-point in a project like this when the commercial momentum can take over. It's important to prepare for this and see this as a positive step.

More specific lessons learned in this project

Throughout the project the complexity of cold chain monitoring, its importance, and the need for thermo-stable products (as the best potential solution for securing good quality) were confirmed. The project also led to a better notion of the various cold chain initiatives and types of solutions that already exist; and it was seen how poor these solutions fit the MSF cold chain.

The taken user-centered approach required the mapping of existing processes, which had great value as it allows for a better understanding of the current issues faced within the organisation

Also the involvement of field staff in this project turned out to be of great value, as with their feedback better insights were obtained in what works and what does not, and it was seen that sometimes it are small details that are crucial for success.

In this project we experienced that taking a more bottom-up approach may cost more time and effort, but that it also contributes a lot!

12. CONCLUSION

The processes and methods used in this project have shown that there is a tremendous advantage to MSF being involved in product development at an early stage. The benefits of catalysing change in collaboration with industry and academia allow for the operational needs of the organisation to be fully considered and the final product tailor made to fit these. In addition, the opportunity to fully evaluate the existing systems which are used within MSF provides a wealth of information and insights that would otherwise go largely unnoticed.

It remains to be seen if and when the indicator will reach market and at what price. However, to have produced a prototype which has garnered such clear commercial interest shows that there is a massive potential. Through involvement in the design process, there is potential to secure a reduced market price through licensing agreements — exemplifying the value of MSF's expertise in the humanitarian field.

The SIU and OCA would like to thank the following actors for their input and support on the project to date:

ACREO — Beneli — TU Delft — PATH — TSS