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A New Approach for Temperature Monitoring in a Changing Clinical Supply Chain Environment

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New trends are changing the clinical supply chain

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The clinical supply chain of investigational medicinal products (IMPs) is complex. The time from designing and packaging a kit through to it reaching the patient can take several months, and as well as the sponsor involves many stakeholders such as Contract Manufacturing Organisations (CMO), Distribution Centres including Logistics Service Providers (LSPs) and Clinical Sites. The clinical supply chain frequently includes different countries, several transportation legs and many days and months with product sitting on a shelf in different storage locations. Thus, management of the temperature exposure of a sensitive IMP is critical. Temperature deviations can put patient's health at risk, as well as their participation in the study due to non-availability of kits. Following a temperature excursion, kits would be quarantined until the viability is determined, which could result in their destruction if they were deemed unfit for use. An IMP supply chain where the temperature control is robust is therefore a vital asset.

Increasingly, we are seeing clinical trials that involve individualized/personalized medicines, such as gene therapies. These trials require a totally different clinical supply chain by the nature of the products and therapy areas. Speed to the patient is crucial. Additionally, in an increasingly competitive world and with spiralling development costs, there is more time pressure shortening the time for patient recruitment. Clinicians and Sponsors need to consider: How can we get patients on board faster? However, it is not just about getting the patients into the studies; there is a need to improve patient retention, how can clinicians keep patients in the study - in particular for lengthy studies? Moreover, how can we increase convenience for the patients?

In recent years the 'patient's voice' with respect to clinical trials is increasingly being heard; they are requesting more convenience, more 'virtual communication' (fewer site visits, more electronic communication) and less travelling. With patient recruitment and increasingly retention being a concern, many sponsor companies actively involve patient groups in various clinical trial design aspects. Additionally, in support of convenience, global patient surveys[1] have indicated that patients would value the delivery of IMP's to their home. Therefore, we see an increasing need and benefit for delivering IMP's Direct to Patient (DTP).

This increasing trend of DTP intensifies the challenge of managing the complete clinical supply chain:

- The LSP or courier may not always be aware that they are carrying pharmaceuticals: so how can we be sure, that the IMP has not been exposed to temperatures outside of its range and thus confirm the viability of the product. How can the status be documented?
- The patient should be aware of the storage conditions of the product via information provided by the sponsor and site teams. However, how can we expect the patients to review the temperature when it is delivered directly to them?
- Once delivered, how can patients monitor temperature efficiently while storing the IMP at home, if required? When they finally use the IMP - how can they decide at the point of administration, if it is still safe to use, if it is a temperature-sensitive product?

Why monitor temperatures?

Biological and chemical medicinal products are in many cases, by definition, temperature sensitive. There are 40+ Good Distribution Practices (GDP) regulatory directives around the world, most recently the European Commission's Guidelines GDP (2013/C 343/01), state requirements for maintaining product integrity throughout the lifecycle of an IMP, using electronic temperature recording devices. Although using a summation of the total time out of range is not part of these regulations, there are other industry groups, namely the Parenteral Drug Association (PDA), that have outlined in their Technical Report 53 how using a 'stability budget' can provide visibility into maintaining proper temperatures in end-to-end clinical supply chains.

[1] The recent report on the ISPE Project Concerning Patient perceptions of IMPs found, that 75 % of patients would find it helpful to have their clinical trial medication delivered to their homes.

In the past, GMP and GCP responsibilities have typically stopped at the clinical site when the IMP was handed over to the patient. The 'last mile', transportation to the patient's home, was never monitored. Neither was the storage at the patient's home, since the consensus has always been 'you cannot manage the patient'. ICH E6 (R2) 5.13.3 states that 'the investigational product(s) should be packaged to prevent contamination and unacceptable deterioration during transport and storage'. However, this never was interpreted to include storage at the patient's home.

With an increase in DTP deliveries, the scope of GMP and GCP could shift towards temperature monitoring by the couriers and the patient. Therefore, anything that gives the patient a clear 'OK' or 'Not OK' will support compliance and help ensure patient safety.

What is a stability budget?

The 'stability budget' defines ideal transport and storage conditions and a budget of acceptable excursion hours above and/or below the 'ideal' before a product loses stability. This stability budget has been established over time by the product innovator company through numerous stability studies, combining relevant information from temperature studies with available data from the stability testing, to determine the amount of time a product can spend out of its labelled storage conditions without risk to its safety, quality or efficacy. As a product moves through the various phases of clinical supply chain and life-cycle, parts of this budget may be used-up by small temperature deviations – typically during loading, unloading and transit points, from one step to the next, but also during packaging, manufacturing, or storage – small temperature deviations may happen. Such deviations along a clinical supply chain are often called '(Total) Time out of Storage (Conditions)' (TOS). If the TOS is deducted from the original Stability Budget, we can calculate the 'Remaining Stability Budget' (RSB). If at the end of a clinical supply chain there is RSB, an IMP is safe to use – at least from a temperature perspective. If there is no RSB, it cannot be dispensed or used. When handing over an IMP to a patient, the healthcare professional must be assured that there is enough RSB to dispense it to the patient. To allow dispensing and handover to patient, a minimum RSB should be defined by the Sponsor. Current practices do not provide this level of detail to clinical sites, but if it were available could also help in decision making in real-time if a small temperature excursion has occurred at the site and patients are waiting.

Stability Budget – Time-out-of-Storage (TOS)
= Remaining Stability Budget (RSB)

RSB	Status
RSB > 0	**Ok to use**
RSB < 0	**Do not use**

Options of clinical supply chains of IMP's

When supplying IMP's to patients, there are various different ways to define the clinical supply chain (*Fig.1: IMP Supply Chains*).

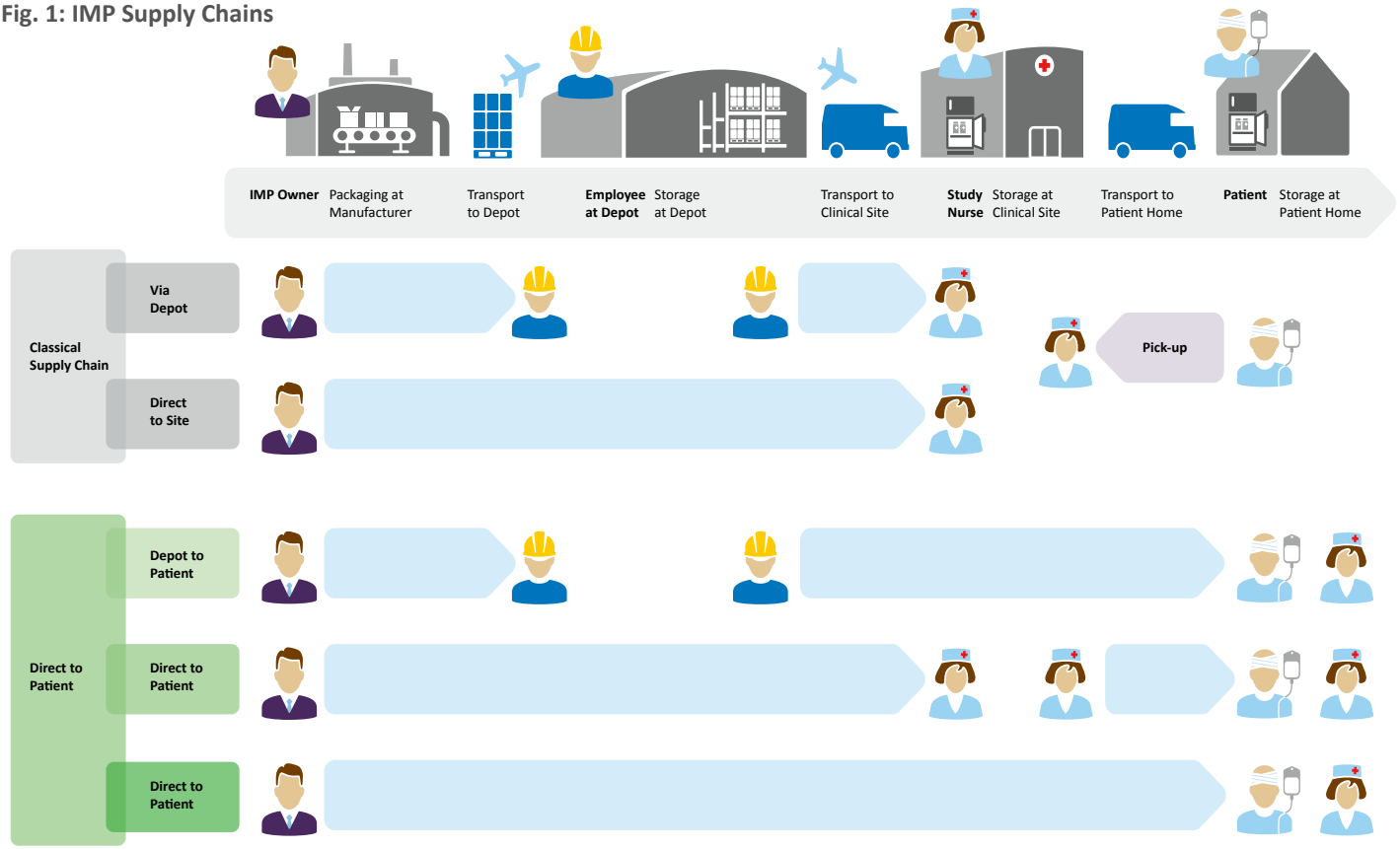
There are some questions we need to examine and answer about clinical supply chains:

> What are the reasons for different classical clinical supply chains (why via Depot, why direct to site?)
> What are the reasons for Direct to Patient shipments?

The design of an appropriate clinical supply chain has to take many factors into account, not least the location and number of countries, number of clinical sites, amount of available product and its shelf life. Sponsor companies may use CMOs to support them as they lack the appropriate manufacturing or packaging capability/expertise or resources. In addition, in order to facilitate the logistics aspects, the sponsor or CMO may also have to consider countries where regional or local depots may be required to accommodate import requirements, and to ensure the IMP reaches the clinical site promptly and efficiently without the need to manufacture large quantities of overage.

In the clinical trials marketplace there is increasing pressure to complete studies in a shortened timeframe to optimise 'time to market'. Although the regulatory landscape is still developing in this area, various factors have resulted in many studies including an option to ship IMP DTP. The increasing global spread with many studies being undertaken in a growing proportion of third world countries, or other in areas of the globe where patients may need to travel long distances to reach the clinical site, is also driving this demand. Additionally, in the developed world, patients are requesting 'choice' and can often be time-poor; visiting a clinical site just to receive medication with no study investigations is not something they wish to agree to. The increasing involvement of orphan drugs or customised medicines, coupled with the role of technology and home care, is also playing its part. Some clinical trials have been run 'remotely', or involve the use of study nurses visiting patients' homes for drug administration or assessment purposes. However, this patient centric approach is not without its challenges.

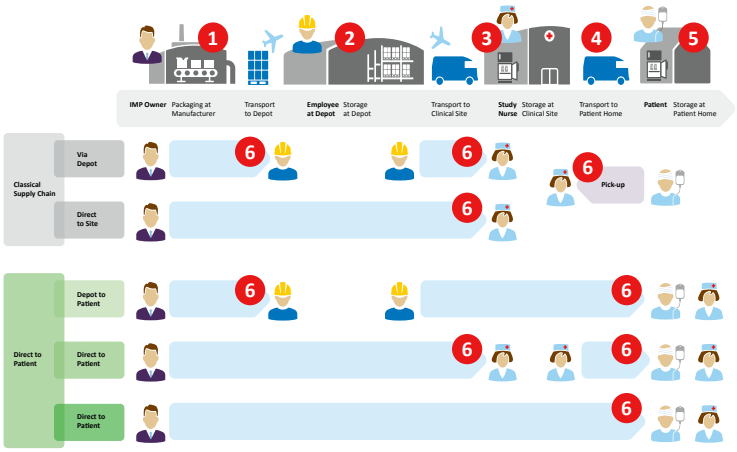
Fig. 1: IMP Supply Chains



The 'temperature monitoring challenge'

Regardless of which design option is chosen for the clinical supply chain, the challenge of keeping a managed cold chain and/or to continually updating the Time out of Storage Conditions (TOS), remains the same. DTP is emphasizing some of the challenges for the last mile.

Monitoring challenges at 'the last mile':



1. Packaging must comply with GMP requirements and should never be stored outside label conditions. However – as part of a well-documented risk-based approach – a manufacturer may expose IMP outside label condition during packaging for a limited period. Thus, while packaging clinical kits (which may be partially performed temperature environment) time must be taken into consideration in the RSB.

2. Storage at Depot must comply with GMP and GDP requirements. If a temperature deviation happens at a depot or in transit to the depot: How is this time taken into consideration in the remaining stability budget of each single clinical kit affected?

3. During transportation to and storage at a clinical (or investigational) site: How is temperature monitored; are temperature deviations taken into consideration in the RSB of each single clinical kit affected? How are you ensuring the viability of the product when you hand it over to the patient and how is this documented?

4. During transportation to the patient (regardless if performed by a LSP or the patient): Is temperature monitored at all? Has this been risk assessed? Was this risk assessment included in the application to conduct the trial?

5. During storage in the patient's home refrigerator: Is temperature monitored at all? Has this been risk assessed?

6. At the very end of the clinical supply chain, before using an IMP: How does the individual know, that the IMP is still safe to use? In case of ALARM, who should they contact? How will the Sponsor be informed?

It is difficult in 'classical' IMP clinical supply chain to keep track of the RSB. The more hand-over points, the more risks and the more complexity: it gets more difficult to keep track of the temperature excursions and the RSB. Today this is often performed manually on a paper or an Excel basis: File a batch record, deduct planned temperature excursions and document unplanned excursions. However, once a batch gets split up throughout the clinical supply chain this manual process is not only time consuming and expensive – it is a process which is very fragile, error-prone and puts quality at risk.

This is one benefit DTP offers, as it may reduce the hand over points when shipped directly from the depot to the patient, or the transportation to the patient's home is performed by a professional and trained person, taking care of defined transportation conditions and risk assessing the processes.

Consideration of the General Data Protection Regulation 2016/679 (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA) should be included in the review of the feasibility, as the direct to patient supply will necessitate knowledge of the patient's name and address. How can this be undertaken within the scope of the current legislation and the GCP requirements? The informed consent must contain information on the detail of who will have access to patient's identifiable information, e.g. the couriers as well as their healthcare professionals.

Impact of DTP on the 'temperature monitoring challenge'

What is special about shipping, handing over, storing and documenting temperature sensitive IMP to/at patients' homes?

The typical shipment size of DTP shipments is small (e.g. usually a single or at most a handful clinical kits) compared to site or depot shipments in the clinical supply chain (e.g. several kits at one time shipped using some form of refrigerated container/cool box or even palletized delivery of multiple cool boxes). Effective data loggers typically used to monitor IMP shipments are built for these larger shipments and are not designed to monitor individual kits.

How is the IMP getting to the patient? Will the study nurse pick-up the IMP at the site and bring it to the patient? Will the patient pick-up the IMP at a nearby pharmacy? Or will the IMP be delivered to the patient with a courier/logistics provider (and when the study nurse arrives at the patient's home, the IMP is already there)?

When a shipment is handed over to the patient at their homes with some kind of a temperature logger, the temperature status (including the RSB) needs to be documented. The responsibility and process for recording the status of the product on dispatch to and arrival at the patient's home needs to be clearly documented and ideally the 'delivery agent' would be trained in these processes. This step should not be entrusted to patients themselves as most will not have the equipment, training or knowledge on temperature-sensitive shipments. In addition, for some incapacitated patients, they may lack the ability to read classical temperature data loggers or upload information to a database. In the case where a HealthCare Professional (HCP) is also involved in the patient's homecare, the patient may be asked to keep the package containing the IMP until that visit.

Ideally, the HCP has a tool which is intuitive and simple to use. This tool should allow them to document that the IMP is safe to use, and still has RSB before handing it over to the patient. Reading a min/max thermometer from a patient's fridge could be an option - but this would not confirm for example that the patient has always kept the IMP inside the fridge. It will be important that whoever is involved in the administration of the IMP has a process for reporting to the Sponsor in cases where there is no RSB. Additionally, there would need to be a process for receiving urgent resupply to treat the patient in this scenario.

In today's electronic world, Interactive Response Technology (IRT) plays a key role in managing and monitoring many aspects of the clinical trial process, including the location, availability and status of IMP. Can the IRT be used to monitor DTP supplies? How would it be kept up to date? Is the patient motivated and capable of doing this?

Two monitoring options

Monitoring temperatures along the clinical supply chain of an IMP up to the patient (and even during storage at patient's home) is important but challenging. There are two fundamentally different options to monitor and keep track of the remaining stability budget: 'Measure & Puzzle' vs. Life-time/Kit-level indicator. *(Fig.2: Two temperature monitoring options for clinical supply chains)*

'Measure and Puzzle': Option A is what most companies are doing today – at least partly. Depending on the study and depending on the agreements with CRO/CMO's the responsibility of temperature monitoring can be organized in different ways. Depot shipments, but also site shipments, are typically monitored with temperature data loggers – at least to the point where an IMP is handed over at the clinical site or to a patient. However, the challenge with this option is: how to put the puzzle pieces together.

Assume that a large quantity of clinical trial kits is shipped in several large containers to a depot. One of these containers experienced a temperature deviation during the shipment. After being re-packed and combined with other IMP, one of the kits experienced another deviation in a later clinical supply chain step, when shipped to the clinical site. How can the two deviations be combined? Even if the data loggers from the two shipments are from the same manufacturer: How difficult is it to access the information of which kit has been in which container? Are the two files stored in the same system? Today sponsors often have to put the 'puzzle pieces' together with paperwork or Excel sheets. *(Fig. 3: Difficulties in combining temperature data)*

Fig. 2: Two temperature monitoring options for clinical supply chains

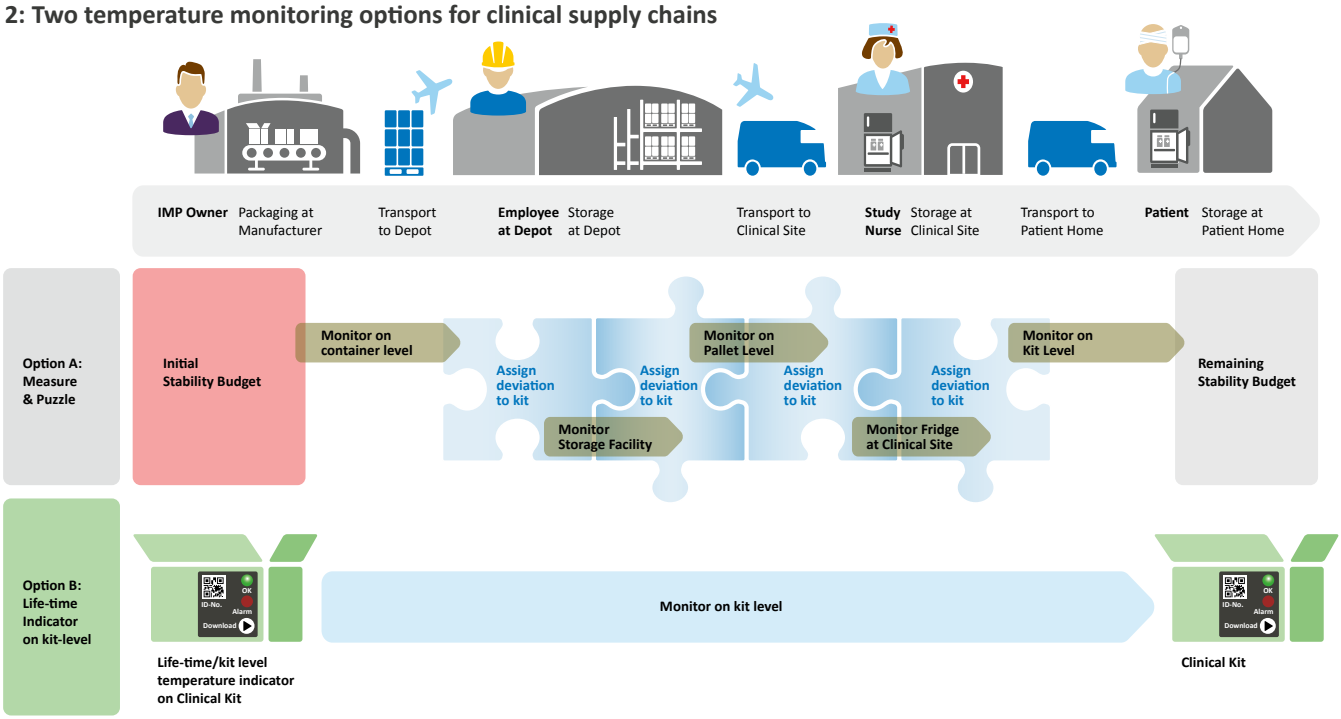
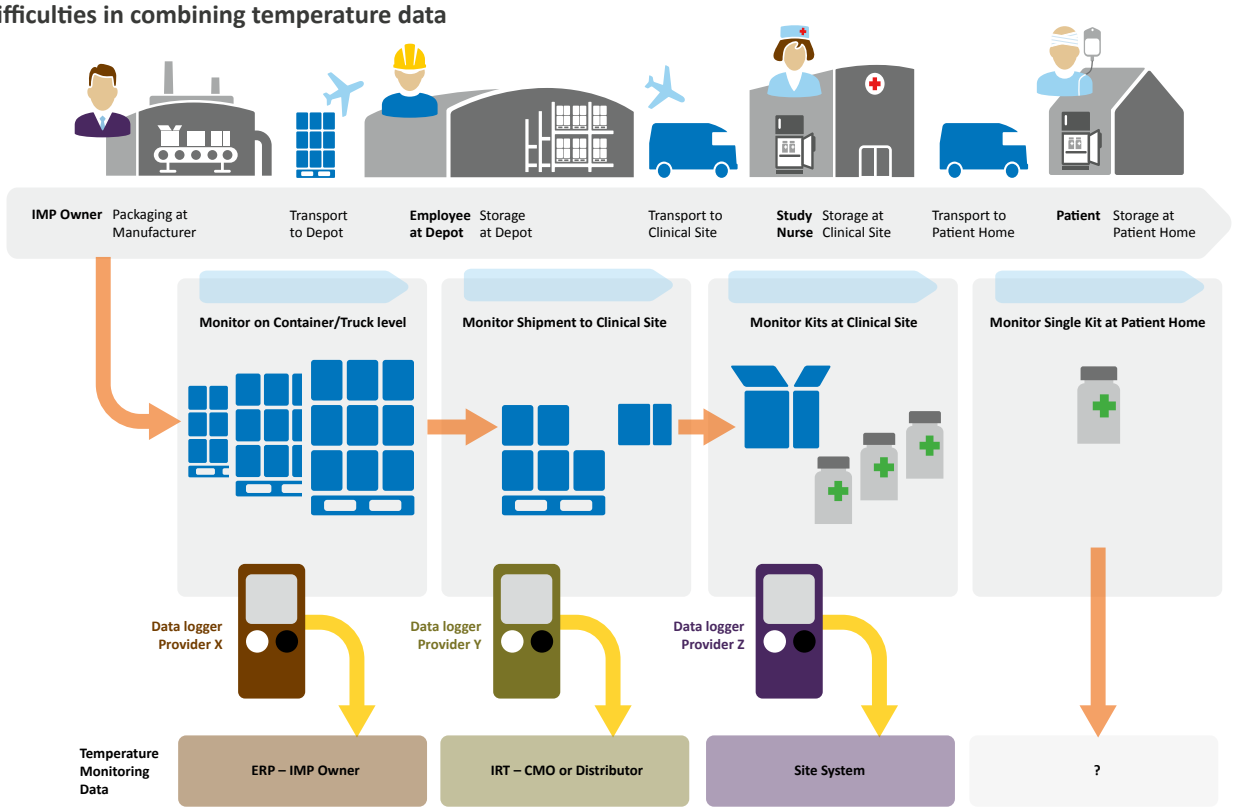


Fig. 3: Difficulties in combining temperature data

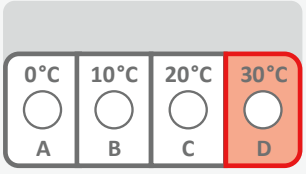


A Life-time/Kit-level indicator (Option B) is a fundamentally different approach. It equips each clinical kit with an individual visual temperature indicator at a kit level and monitors temperature during the entire life-time – from packaging/labelling to patients' home and final use. It is therefore the obvious choice for several clinical trial scenarios, including DTP shipments, since the transport to the patient – as well as the storage at the patient's home – can be monitored without interruption.

Requirements for kit-level indicators

Monitoring temperatures at a kit-level is not new. Chemical indicators which are applied to box level have been available for more than 20 years now. However, they are typically not precise enough for IMPs and are difficult to validate - therefore not considered GxP-compliant.

Chemical vs. electronic indicator (schematic illustration):



Chemical Indicator

Electronic Indicator

What are the requirements for an electronic kit-level indicator?

- Must be developed and produced according to GAMP5® guideline[2] and equipped with a unique ID-number to allow traceability
- Must be low cost, since tens of thousands of kits may need to be equipped (e.g. <<5 USD)
- Must be thin (<3mm) and small enough for use at the kit level (< credit card size)
- Can be attached directly to kit with self-adhesive back
- Monitoring can be started easily without equipment
- Has enough battery capacity to cover the entire life-time of a typical kit (up to 4 years)
- Has a calibrated and accurate temperature sensor (with a NIST-traceable[3] calibration certificate)
- Can continuously monitor temperature and keep track of remaining stability budget
- Can easily show status visually (OK to use?) at any time without additional equipment and is also intuitive to use also for healthcare professionals and the patient.
- Can document and archive the status in compliant way (no manipulation possible) and allows for easy feedback to sponsor in case the stability budget is used-up (ALARM)
- Keeps track of statistics (time per temperature zone, highest and lowest value) as well as date & time of alarm for further analysis by the sponsor.

[2] GAMP5® is a well-known development and production guideline for suppliers to the pharmaceutical industry developing and producing of electronic equipment and software.

[3] NIST is a well-known (US) standard of calibration which is traceable to the (USA) national standard. Other well known standards are DAkkS (Germany national standard), or SAS (Swiss national accreditation standard).

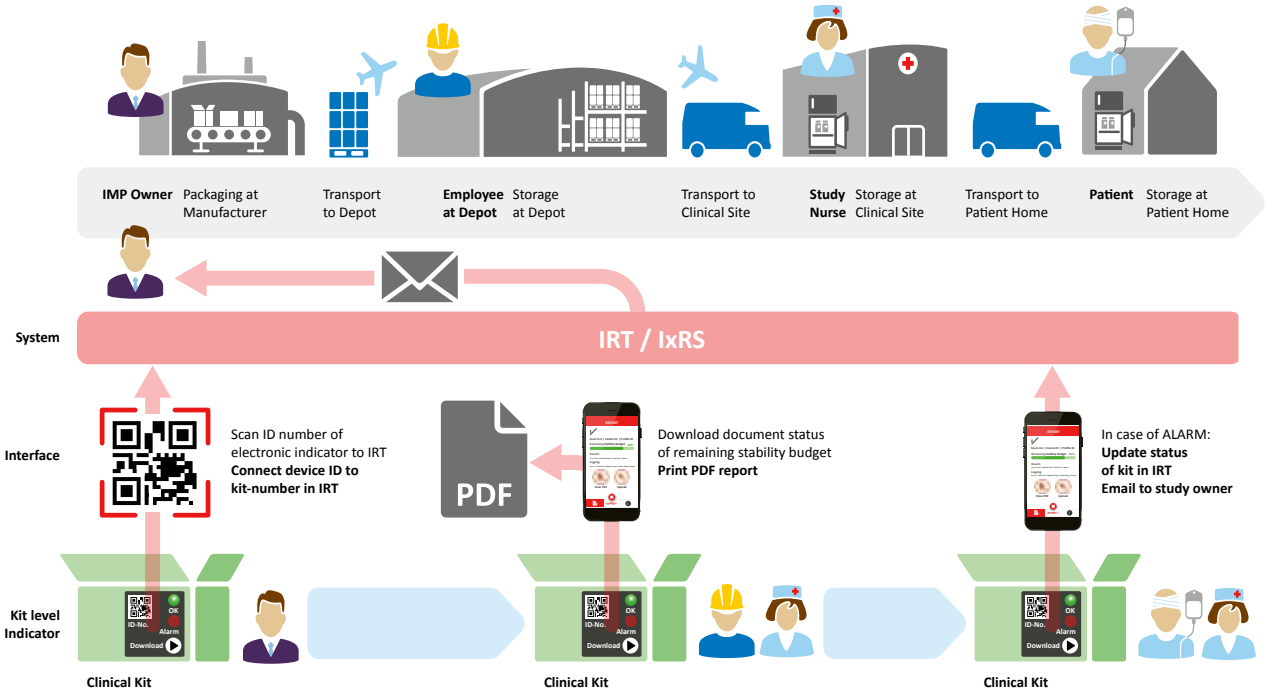
To bring all these requirements into one device is not an easy task, in particular since there are conflicting requirements (e. g. extreme long life-time vs. small & thin). The ultimate dream would be to have everything in a printed label (printed electronics). Unfortunately, this is not possible today since, for example, printed batteries only deliver enough energy for a few days (but not for a few years). However, there are solutions on the market today, which cover all those requirements. From a monitoring perspective, such a device could simplify the management of standard clinical supply chains as well as DTP shipments, as these devices fully support patient safety.

Role of IRT

IRT systems ensure randomization and drug management functions for investigational sites. These systems typically know the status of all clinical kits through the entire clinical supply chain. If a kit is damaged or loses its complete stability budget (= has a temperature ALARM), the status of the kit in the system is changed. Using IRT systems for Direct to Patient shipments adds potential difficulties as well as opportunities:

- If no professional personnel are available, shipment and hand-over-process to the patient must be simple, easy and must be supported by IRT
- Status of clinical kits must be reported back to the sponsor
- IRT allows information about the status of the kit to be available at the point of hand-over to the patient, (scanning the kit and transferring the data into the system) thus it increases patient safety, as it is documented that the kit was within specification when handed over to the patient. Additionally, action can be taken when this is not the case, e. g. trigger another shipment, don't hand out the IMP.
- When the kit is returned it could be scanned and checked if there was a TOS during storage and usage at the patient's home. Depending on the patient and the storage, it might not be possible to store used kits in refrigerated conditions and to transport them back. This would be revealed as early as possible. The scan & data transfer could be performed by the Courier or when received by the depot.
- The patient could be asked to scan the kit before starting to take the medication, through a specific Smartphone App, thus informing the system and enabling notifications as described above, including telling them to stop taking this kit and providing a replacement (automatically through the IRT). This could also enable better patient compliance calculations about when the patient has started to take / use an IMP kit.
- It is possible to scan all kits when the DTP shipment is dispatched, to ensure the shipped kits had no temperature excursion which might not be known yet and provide replacements when required. This will increase patient's safety and, as the shipments are relatively small; this should be possible and will act as an additional QC step.

Fig. 4: Linking an electronic indicator with an IRT



> The Smartphone App could be used as an extended device to communicate with the patient like an ePRO[4] device, informing patients that a shipment was triggered for them, etc.

Moreover, it is important to keep track of the (temperature) status in the IRT system. To make this feasible, it is imperative to link the device ID of the electronic indicator with the kit ID. As you can see from the graphic on the previous page *(Fig. 4: Linking an electonic indicator with an IRT)*, this could be done via scanning the data matrix during packaging, labelling or distribution. Once this identification between device and kit is established, it is simple to update its status later in the process without administrative effort. If a download is possible using a standard Smartphone App, documentation anytime and anywhere in the process would become possible, and enable additional patient safety checks and up to date information for the study team.

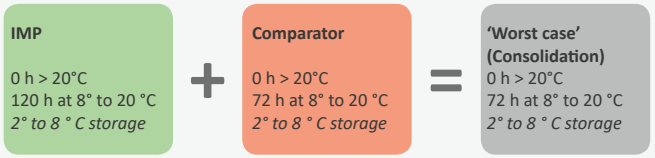
Complications

Complications that need to be considered in using a lifetime/kit level:

Complication	Recommendation
Packaging or kit set-up does not allow the attachment of one indicator per kit (e. g. for cost or size).	Use a 'flag-label' which offers enough place for all required labelling information, as well as the indicator itself.
IMP has unknown stability budget (or stability budget cannot be used) at the time of packaging.	Use the defined storage conditions as strict alarm limits (e. g. 2–8°C). Extending a stability budget on clinical kits of a running study is a complex task that goes beyond the scope this paper.
Patient does not have access to smartphone technology.	Ensure HCP is available at the home during administration to confirm viability.
In a double blind study a comparator agent has different (or unknown) stability budget to the IMP.	Use the most stringent controls between the products and consolidate the stability budgets to a 'worst case' (see example below).

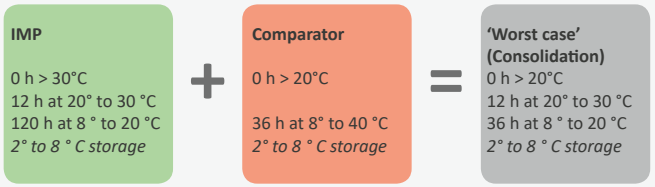
Examples of a 'worst case consolidation' of two stability budgets where the products are recommended to be stored at 2° to 8°C.

Example 1



In this first example we have an IMP and a Comparator with the same temperature limits but just different numbers of allowed excursion hours in the range between 8° and 20°C. Defining the worst case is simple: pick the lower number of allowed excursion hours (stability budget).

Example 2



In this second example, the IMP has three levels defined up to 30 °C while the Comparator has fewer hours but a larger range (up to 40 °C). The worst case consolidation is to take the highest limit from the IMP (0 h > 30 °C), the middle range from the IMP (12 h at 20 ° to 30 °C) and take the smaller amount of hours from the Comparator in the lower range (36 h at 8 ° to 20 °C).

Summary

In the past years, the industry has brought the processes of temperature controlled bulk shipments close to perfection, with sophisticated data loggers and validated shipping containers. In this age where patients are much more aware of trials and where we need to go further for patients, we need to think about new ways of bringing IMP to the patient. Patients are much more technologically aware, which allows the use of modern technologies to facilitate a DTP supply.

The Clinical Supply Chain is long and complex, with DTP adding new challenges but also new opportunities for sponsors, sites and patients. Technologies are available to overcome those challenges and make the benefits accessible – in temperature monitoring, mobile applications as well as in IRTs. However intuitive tools, clear SOP's and training are needed to make the processes safe, efficient and as simple as possible for the users.

[4] An electronic patient-reported outcome (ePRO) is a patient-reported outcome that is collected by electronic methods. ePRO methods are most commonly used in clinical trials, but they are also used elsewhere in health care. As a function of the regulatory process, a majority of ePRO questionnaires undergo the linguistic validation process (Source: Wikipedia).

About the Authors

Note: the authors' contributions are based on their individual knowledge and expertise; this article should not be construed as a statement or opinion by Elpro, Trial Brain, SimplyESW, Boehringer Ingelheim, Novartis or NHS Greater Glasgow & Clyde on this topic.

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