Investigator Initiated Trials (IIT) – Considerations and Guidance from the Perspective of Clinical Trial Supplies and GMP

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This Concept Paper represents industry best practices based on the experiences and input from the individuals listed below and does not reflect the views of any one individual or company.

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1 Introduction

Conducting a clinical trial is a complicated process because of the many factors to address and the numerous entities involved. One such area is management of the interaction between pharmaceutical companies and investigators/non-commercial sponsors in the planning and conduct of Investigator Initiated Trials (IIT). The aim of this Concept Paper is to offer best practice advice for early identification of the minimum information required by the supply chain roles within the pharmaceutical company/manufacturer, owner of the Investigational Medicinal Product (IMP) compound. In addition, the requirements to be fulfilled before an IMP can be supplied to the sponsor/investigator are reviewed. This may help pharmaceutical company/manufacturers and investigators more easily execute the expected level of control and comply with current regulations.

This Concept Paper is designed to give a better understanding of the challenges and requirements linked to IITs and to offer guidance to pharmaceutical companies/manufacturers providing medication to a sponsor, as well as to non-commercial sponsors sourcing medication independently.

The recommendations and advice given in this document are derived from regulations on GMP and Good Distribution Practice (GDP) in the European Union (EU) [1, 2, 3], but may also be useful for the supply of IITs in countries outside of the EU.

2 Background

Investigator initiated trials, also referred to as IIT, IIS (Investigator Initiated Studies) or IST (Investigator Sponsored Trials), have scientific and medical merit developed and sponsored by an independent investigator or academic sponsor. An IIT may be a clinical or non-clinical study conducted without the participation of a pharmaceutical company, for which the IIT sponsor may be requesting pharmaceutical support in the format of either funding, drug product, or both. This Concept Paper covers clinical studies and situations where drug product support is being requested from a pharmaceutical company for an authorized or non-authorized medicinal product (authorized means commercial product).

The sponsor must apply for approval of the study by submitting a Clinical Trial Authorization (CTA) application to the Competent Authority (CA) of the concerned member state that contains either [4]:

- A cross-reference letter to enable the CA to access a previously submitted Investigational Medicinal Product Dossier (IMPD) provided by the pharmaceutical company that owns the IMP. This may refer to a clinical study run by the pharmaceutical company that owns the IMP.
- A cross-reference letter to enable the CA to access an existing marketing authorization
- An IMPD (maybe simplified) provided by the pharmaceutical company that owns the IMP
- A cross-reference letter to enable the CA to access an IMPD submitted by the pharmaceutical company on behalf of the non-commercial sponsor

3 Regulatory Review

IITs are either clinical trials as defined in Directive 2001/20/EC[1] [5] and (future) Regulation (EU) No 536/2014 [6], or low-interventional trials as defined by (future) Regulation (EU) No 536/2014 [6]. As such, IITs fall under all typical regulatory requirements described in Directive 2001/20/EC / Regulation (EU) No 536/2014 [5, 6], such as:

- Review of the CTA application by an ethics committee and competent authorities
- Submitting an application dossier
- Dealing with substantial amendments
- Protecting of subjects and informed consent
- Safety reporting
- Supervision by the sponsor
- Manufacturing and import authorization
- Meeting labeling requirements
- Identifying sponsor and investigator roles and responsibilities

To summarize, the supply of IITs with IMPs, as well as the responsibilities of the pharmaceutical company and the sponsor/investigator, are to be executed in the same manner as for any clinical trial where the sponsor role is taken by, or on behalf of, the pharmaceutical company.

[1] Directive 2001/20/EC will be replaced by Regulation (EU) No 536/2014 [7].

4 Challenges from a GMP and Regulatory Compliance Perspective

The challenges for the supply chain roles are:

- Qualified Persons (QPs) releasing the IMP:
  - What documents or cross reference are to be used by the sponsor/investigator for the CTA?
  - What documents or cross reference have been approved by the CA?
- Is there a process in place to ensure that there is a communication plan between the sponsor and the manufacturer? This must include all necessary notifications and/or approvals by the CA and/or Institutional Review Board (IRB)/Independent Ethics Committee (IEC) before initiation of the trial and shipment to site. The QP performing certification needs to receive information on any CMC- (Chemistry, Manufacturing, Control) related deficiency letters and/or confirmation that the CTA application has been authorized by the CA [5].
- Development of a contractual document to ensure that GMP-relevant aspects are covered between the pharmaceutical company and the sponsor/investigator (e.g., supply agreement, main contract, QAA)
- Consideration of what type of IMP is to be supplied to the sponsor/investigator (authorized, unauthorized, bulk drug product with or without primary packaging, fully finished product), and how it affects the QP release process
- Agreement on roles in set up, translation, approval, and submission to the CA of trial-specific label text, including trial number and sponsor details
- Any further services to be provided by the pharmaceutical company to the investigator such as a central depot, shipments to site(s), Interactive Response Technology (IRT)
- Supply and re-supply strategy during trial progress (depot/site stock oversight, use-by-date, etc.)
- Consideration as to how responsibilities are shared and communicated:
  - Will there be shipment of IMP to the investigator, to a central depot, to additional local depots, and/or to sites?
  - What are the instructions for storage and handling of IMP at the investigational site? What is the process for dealing with temperature excursions, deviations, and product complaints from sites?
  - What are the processes for expiry update, retest-date extension, and re-supply procedures?
  - What is the process for a recall?

5 Survey

A survey was performed among the companies represented in the ISPE Community of Practice Investigational Products working group [8]. The questions and corresponding results are:

A. **How many IIT studies are initiated per year?** Among the companies interviewed, approximately half of the respondents support 1 – 25 IITs per year, while the rest supports approximately 50 – 100 IIT studies per year.

   While this is still a small number compared with the amount of commercial clinical studies pharmaceutical companies perform per year, it is significant enough to consider making procedural improvements and creating standards for departments dealing with IMP supply and IMP quality.

B. **Types of IIT studies supported by pharma companies?** The majority of the IITs performed are open-label studies and are often a single clinical site, with most of them performed within the EU or US. Other types of studies are conducted with significantly less frequency, e.g., open-label studies in other regions, international and/or multisite open-label, or double blind IITs.

C. **Product types supplied by pharma companies?** The preferred and most frequently used option for a pharmaceutical company is the authorized product in its original container for a national IIT, and repacked and/or re-labeled authorized products for multinational IITs. Some of the companies support IITs with unauthorized products as well as with placebo; however, bulk product, intermediate products, and comparator products are rarely supplied by pharmaceutical companies for use in IITs.

D. **Who performs packaging and labeling of IMP?** If packaging and labeling of the product to be supplied is necessary, most of the interviewed companies perform this either in-house or source it to vendor companies through their clinical trials supply unit. Few companies allow their medical department to outsource this process step, or leave it to the sponsor/investigator of the IIT to arrange.

E. **Which legal entity's QP performs final QP release?** As a subsequent step, the final QP release is usually done under the responsibility of the IMP QP of the pharmaceutical company, and only in rare cases by an external QP, contracted either by the pharmaceutical company or the sponsor/investigator. Therefore, the main burden of the release work and decision resides within the pharmaceutical companies supplying the product for IIT studies.

F. **Who provides the IMPD or a cross-reference letter?** In order to support the CTA application process for an IIT in the case of IMPs, usually cross-reference letters to previously submitted IMPDs are provided by the pharmaceutical companies. Summaries of Product Characteristics (SmPCs) are often used when authorized products are supplied. IMPDs are rarely provided to external sponsors to submit to the CA.

G. **Responsibility for QAA?** The majority of companies have a QAA, either as attachment to the main contract or as separate document. In most cases. Medical Affairs leads the setup of the QAA. In some companies, QAAs are also signed by the IMP QP if the company's clinical supplies unit is involved in packaging and labeling activities.

H. **Responsibility for IMP logistics?** When it comes to storage and distribution of the products, most of the companies arrange for it through their own distribution functions. Less frequently depots contracted by the investigator are used.

I. **Provision of IRT services by the Pharma company?** IRT systems are often not provided by the pharmaceutical companies. Where IRT support is considered beneficial, a critical consideration would be the interface connection between the IRT vendor and the investigator.

J. **Responsibility for IMP supply chain management within the Pharma company?** When considering the roles for IMP oversight; the Medical Affairs department is often the primary contact to the sponsor/investigator, while the Clinical Supply Unit (CSU) receives the order, performs packaging and labeling, and oversees the stock at the (company's) depot. The sponsor/investigator usually manages the stock at the site, reorders supplies, and communicates temperature excursions and complaints to the CSU or quality department of the pharmaceutical company. As Medical Affairs is the primary contact to the sponsor/investigator, the availability of a robust process and the smooth flow of information between Medical Affairs and the CSU is crucial to set up a reliable IMP supply chain.

6 Key Information to Consider when Setting Up the Supply Chain

The following is considered to be the minimum information required by the responsible supply chain planning unit of either the pharmaceutical company supplying the IMP (e.g., Medical Affairs, CSU, etc.) or the sponsor/investigator:

- Unique study identifier of IIT
- Relevant information of the trial design (e.g., protocol, products, number of patients, dosing regimen, duration of treatment, number of sites, countries, expected enrollment rate, etc.)
- Planned dates for first patient treated and last patient treatment completed

This information allows planning for setting up the proper supply chain of the trial by defining parameters such as product strengths, quantity, use-by-date, use-by-date extension, manufacturing campaigns, delivery date to site, etc.

7 Key Information for Consideration by the Quality Unit

The following is considered to be the minimum information required by the responsible quality unit (GMP QA/QP):

- Unique study identifier of IIT
- Written order according to Annex 13 [2]
- Approved clinical protocol
- Submitted and CA-approved CMC documentation per country (e.g., IMPD, cross-reference letter, SmPC)

8 Case-Specific Recommendations

There might be IITs with special characteristics requiring additional consideration and agreement between the parties.

- IITs where the product will be supplied by the pharmaceutical company to the sponsor/investigator as bulk drug product, not as final packaged and labeled IMP

  Independent of whether an authorized medicinal product or an unauthorized IMP will be used, there should be a discussion regarding any additional manufacturing steps required and who has responsibility for those, as well as assessing their impact on the quality of the IMP (e.g., reference samples, stability testing), creation of relevant filing documents, and final QP release.

  It is generally recommended to supply the bulk product in a primary container for which the pharmaceutical company has stability data in order to avoid quality considerations regarding stability or shelf life following primary packaging by the sponsor/investigator.

- IITs where the IMP is authorized in one member state but not in the one used

  It is recommended to clarify upfront what CTA application requirements apply, e.g., is a translated SmPC acceptable; will a cross-reference letter to a submitted IMPD be used or is a separate IMPD to be submitted on behalf of the sponsor.

- IITs where a combination of multiple products is to be tested

  The sponsor/investigator may need to contract with several companies in order to establish the supply chain for the study, or may direct sites to use their own commercially procured stock, as appropriate. The sponsor/investigator is responsible for ensuring that the documentation required for the CTA application process is obtained and submitted for each product in their study. Sourcing requirements may be challenging when multiple parties are involved, and responsibilities must be clearly defined for all parties.

- IITs using an authorized medicinal product outside the authorized indication

  Local regulations should be checked to determine whether relabeling as an IMP is needed or if the use of unmodified commercial product is acceptable.

- Use of an IRT system

  Where IRT support is considered beneficial, a critical consideration is the interface between the IRT vendor and the investigator in terms of the randomization and packaging lists. Clear communication plans for the clinical trials packing unit are needed as well as plans to maintain any blinding.

It must be emphasized that any IIT-specific modification of a medicinal product in its final commercial package or of an established (clinical) packaging design of an unauthorized product creates additional hurdles, capacity issues, and costs both on the pharmaceutical company side as well as on the sponsor’s/investigator’s side, and should therefore be carefully weighed against the benefit expected by the modification.

9 Quality Assurance Agreement (QAA)

The term used in this document is QAA, however other terms are often used and are considered equivalent to QAA (e.g., technical agreement, technical and quality agreement). The purpose of the QAA is to provide sufficient detail on the pharmaceutical responsibilities and their delineation between the pharmaceutical company and the sponsor/investigator.

While there is usually a contract available between the pharmaceutical company and the sponsor/investigator regulating the business relationship, the regulatory and quality responsibilities are not necessarily covered. A QAA between the pharmaceutical company supplying the product and the sponsor/investigator of the IIT, covering the following aspects, is mandatory in the EU[2] [2, 9] and strongly recommend for IITs performed outside of the EU:

- IIT Supplies

  There should be a description of type of product and general terms for the supply strategy unless fully described in the contract.

- GMP aspects of the IIT supplies (items listed below are not exhaustive):

  - Define responsibilities for the supply chain as appropriate (e.g., manufacture, blinding, packaging and labeling, QC testing, stability testing and expiry dating, retention times of samples and documents, storage, transport, return, destruction, etc.)

  - Define responsibility for creation and approval of GMP documents, and for documents to be provided between the parties

- Responsibility for applications for approval to regulatory authorities and ethics committees

- QP responsibilities and relationship with sponsor/investigator:

  - QP declaration as appropriate in the case of an IMP imported into the EU

  - QP confirmation as appropriate for process steps performed by the pharmaceutical company

  - QP certification, including regulatory compliance, confirming that the IMP released is in compliance with information stated in the approved IMPD, the referenced IMPD, or the referenced SmPC

  - Ensuring availability of all regulatory approvals to initiate the study, e.g., CTA, ethics committee approval (regulatory release by the sponsor)

- Product complaints and recalls management process

  This process should address information exchange and reporting needs, timelines, and shipment of recalled product.

[2] Currently Annex 13: Investigational Medicinal Products [2], will be replaced by C(2017) 8179 final: Detailed Commission guidelines on good manufacturing practice for investigational medicinal products for human use, pursuant to the second subparagraph of Article 63(1) of Regulation (EU) No 536/2014 [9].

- GCP aspects of the IIT supplies

  These include randomization, de-coding arrangements, and pharmacovigilance (unless covered by the supply agreement).

- Audits and inspections by each party and regulatory authorities

  This includes the allowance of auditing the other party, mutual sharing of information regarding inspections planned and performed, required support by the pharmaceutical company during GCP inspections (e.g., storage and transport to site, temperature deviation handling, provision of temperature monitoring documents, etc.), communication and sharing of findings from inspections.

Further QAA attachments are recommended to cover GMP requirements such as:

- "List of contact persons" of both parties, pharmaceutical company/manufacturer and sponsor/investigator

- "Agreed upon sub-contractors" and their contacts if applicable, e.g., for outsourced packaging labeling and/or storage, distribution services

Additionally, it is recommended to describe the duties and responsibilities between the parties in a table, as shown in the example in the appendix (see Chapter 13).

It is possible to have one sponsor/investigator per country or one sponsor/investigator covering several countries (e.g., EU countries plus Canada). In both cases, delineation of pharmaceutical responsibilities should be part of the QAA. A clear definition of roles and responsibilities within the coordination of the IMP supply chain is strongly suggested.

10 Conclusion

IITs play an important role in the interaction between pharmaceutical companies and independent sponsors/investigators. This Concept Paper addresses some challenges in their support and coordination from a clinical trial supply and GMP perspective. The early involvement of the CSU and GMP functions in creating cooperative support for an IIT is highly recommended to ensure the success of these projects.

11 References

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8. ISPE Communities of Practice, International Society for Pharmaceutical Engineering, ispe.org.

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12 Abbreviations

CA	Competent Authority
CMC	Chemistry, Manufacturing, Control
CSU	Clinical Supply Unit
CTA	Clinical Trial Authorization
EU	European Union
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
IEC	Independent Ethics Committee
IIT	Investigator Initiated Trials
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
IRT	Interactive Response Technology
IST	Investigator Sponsored Trials
QAA	Quality Assurance Agreement
QP	Qualified Person
SmPC	Summary of Product Characteristics
US	United States

13 Appendix – Duties and Responsibilities Concerning Provision of Trial Product

The template in Table 14.1 gives guidance as to what aspects to consider when developing a contract to establish the pharmaceutical responsibilities of both parties; however, it may not cover all details and requirements of current regulations, depending on the specific set up of the IIT. It is recommended to take into account current regulations, directives, and guidelines when creating the contract in order to address all aspects relevant for the product to be supplied, and the different IIT scenarios possible. It is prudent to add a similar table to the QAA template between the sponsor/investigator and the pharmaceutical company.

Table 14.1: An Example Template: Duties and Responsibilities Concerning Provision of Trial Product

Responsibility	Company (Medical)	Company (CSU)	Company (QA/QP)	Subcontractor of Company	Institution (Sponsor)	Subcontractor of Sponsor	Comment
Planning and Regulatory Requirements							
Provision of approved and filed clinical study protocol for IIT							
Information on IMP (type of product, identifier, dosage form, strength, primary packaging to company (CSU, QA/QP))							Type of product: authorized commercial product, unauthorized IMP, etc.
Provision of trial product for use according to above-mentioned IIT protocol							
Define the support required for the filing documentation to be submitted to CA, e.g., letter of cross reference, etc.							

Responsibility	Company (Medical)	Company (CSU)	Company (QA/QP)	Subcontractor of Company	Institution (Sponsor)	Subcontractor of Sponsor	Comment
Planning and Regulatory Requirements (continued)							
Application for CTA							Optional text modules for submission of CMC information to CAs: • Cross-reference letter referring to an existing (submitted and approved) IMPD • Quality dossier (IMPD) with respective GMP certificates of production and release sites on behalf of the sponsor (institution) including amendments as needed • Current summary of product characteristics
Provision of cover letter of application for CTA, application form (CTA Modul 1) including the label text, and of approval decision letter of CA for IIT to company (QA/QP)							The information contained herein is needed by the QP for certification of compliance with the filing
Ensuring availability of all regulatory approvals prior to initiation of the study							
Pharmacovigilance							
De-coding arrangements							Depends on final packaging option and who does QP release

Responsibility	Company (Medical)	Company (CSU)	Company (QA/QP)	Subcontractor of Company	Institution (Sponsor)	Subcontractor of Sponsor	Comment
Manufacturing and Release							
Manufacture and quality control testing of bulk product							
Approval of product label							
Randomization							
Packaging and labeling of product including blinding							
Storage of retention/reference samples of trial material in accordance with storage periods as required by applicable law							
QP declaration as appropriate in case of IMP imported into the EU							
QP confirmation as appropriate for process steps performed by the pharmaceutical company							
QP certification of product, including EU GMP compliance, compliance with product specification file, regulatory compliance (IIT protocol, IMPD, if cross-referenced) according to Directive 2001/20/EG [5] and Annex 13 of EU GMP guidance [2]							
Regulatory release by the sponsor							
Storage and Shipment/Distribution							
Definition of distribution path							e.g., directly, through depot or hub, etc.

Responsibility	Company (Medical)	Company (CSU)	Company (QA/QP)	Subcontractor of Company	Institution (Sponsor)	Subcontractor of Sponsor	Comment
Storage and Shipment/Distribution (continued)							
Provision of storage and shipping conditions							
Shipment of product to institution of sponsor/investigator							
Receipt of product at institution by qualified personnel							
Storage, handling, and distribution of finished product to trial subjects							
Return, Reconciliation, and Destruction							
Return and reconciliation of product							
Destruction of used and unused product							
Complaints and Recall							
Mutual obligation to inform each other of quality complaints							
Obligation to inform COMPANY in case of SPONSOR-initiated product recall							
Obligation to inform SPONSOR (institution) in case of COMPANY-initiated product recall							
Obligation to closely cooperate on product recalls							

Responsibility	Company (Medical)	Company (CSU)	Company (QA/QP)	Subcontractor of Company	Institution (Sponsor)	Subcontractor of Sponsor	Comment
Audits and Inspection							
Audit at pharmaceutical company by, or on behalf of, the sponsor (as applicable)*							
Audit at third party manufacturer							
IMP-related support during GCP inspection at sponsor/investigator							e.g., shipment documentation, temperature excursions

Current regulation (Annex 13 to the EU GMP guide) assigns ultimate responsibility to the sponsor ("…sponsors who undertake the ultimate responsibility for all aspects of the clinical trial including the quality of investigational medicinal products."* [2]) while Clinical Trial Regulation 536/2014 [6] and underlying regulations assign the responsibility for the quality of IMPs to the manufacturer (Detailed Commission Guidelines C(2017)8179: *"…For manufacturers to be able to apply and comply with good manufacturing practice for investigational medicinal products, co-operation between manufacturers and sponsors of clinical trials is required."* [9])

CA: Competent Authority
CMC: Chemistry, Manufacturing and Control
CSU: Clinical Supply Unit
CTA: Clinical Trial Authorization
EU: European Union
GCP: Good Clinical Practice
IIT: Investigator Initiated Trials
IMP: Investigational Medicinal Product
IMPD: Investigational Medicinal Product Dossier
QA: Quality Assurance
QP: Qualified Person

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