Received: 23 June 2023 | Revised: 19 September 2023 | Accepted: 20 September 2023

DOI: 10.1111/cts.13655

POSITION PAPER

Academia and industry agreement on a feasibility tool for first-time-in-human clinical trial units

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Funding information
Innovative Medicines Initiative 2 Joint Undertaking, Grant/Award Number: 853989

Abstract

First-time-in-human (FTIH) trials are designed to generate information on the safety, tolerability, as well as the pharmacokinetic and pharmacodynamics profile of new drugs. To ensure the safety of participants, these trials need to be conducted at specifically equipped phase I clinical trial units (CTUs). In accordance with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (GCP) and the European Union (EU) regulatory guidelines, one of the aims of the European Regime Accelerator for Tuberculosis (ERA4TB) project is to

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collaboratively create a feasibility tool, through a partnership between public and private entities, for the validation of CTUs selected to conduct FTIH trials. A feasibility form, encompassing nine sections, was created to gather information on the unit in relation to key attributes of FTIH trials. Collaboratively, industry and academic partners defined the minimal criteria to ensure the adherence of CTUs to the principles of ICH GCP and regulations outlined by the European Medicines Agency (EMA) for the execution of FTIH trials. Subsequently, all CTUs available for the project were assessed for FTIH trial eligibility. The introduction of the certification procedure through the feasibility tool within ERA4TB resulted in the accreditation of the five academic CTUs, which are now prepared to carry out FTIH trials as part of the Consortium. The developed feasibility tool aims to establish open and widely used minimum requirements for the validation of academic CTUs as FTIH units, marking it as the inaugural tool for CTU validation resulting from the collaboration between industry and academia within the ERA4TB project. The established partnership has enabled an innovative and novel way of working.

INTRODUCTION

The journey from initial research to bringing new drugs to the market is an intricate and lengthy undertaking that can extend for a period of 10–15 years.[1] This process of uncovering effective treatments encompasses various stages, spanning from early drug discovery to preclinical and clinical development, and culminating in regulatory approval.[2] To achieve this, it is imperative to conduct clinical trials involving human volunteers to assess the safety and efficacy of novel therapies, drugs, or procedures.[3] Clinical trials are categorized into phases I through IV, with the initial stage, where humans first receive experimental drugs, known as first-time-in-human (FTIH) trials.[4]

FTIH trials apply the insight gained from the preclinical stage, to establish safe and tolerable doses in humans.[5] The aim is to generate initial knowledge on the exposure, safety, tolerability, and the pharmacokinetic and pharmacodynamics profile of new drug candidates by testing them, most frequently, on healthy participants. Given the inherent nature of FTIH trials, a non-negligible element of risk is involved. Due to limited knowledge of the drug candidate, researchers do not have the ability to accurately predict the effects it can have on humans, which calls for special attention to the participant's safety and well-being.[6]

The clinicaltrials.gov database has a total of 4549 early phase I trials registered. About 10% of these are conducted in Europe (Figure 1), and are concentrated mostly in Spain, Germany, France, and the UK (Figure 1).[7] Figure 1 shows the global distribution of the studies. Multicentric studies are included in each region containing sites. It should be noted that registration of phase I clinical trials to the clinicalTrials.gov database is not mandatory nor is it the only clinical trial register available.

International and local laws, along with a variety of guidelines and requirements, have been issued to protect trial participants. The European Medicines Agency (EMA) created a guideline to identify and mitigate risks for trial participants in FTIH. The guideline, revised by the European Commission and representatives from the Member States of the European Union (EU), focuses on risk evaluation, adverse events reporting, stopping criteria, starting dose calculation, and dose escalation rules.[6] In the case of the UK, the Association of the British Pharmaceutical Industry (ABPI) developed its own guidelines for phase I clinical trials, which reflect the relevant EU legislation as outlined in the EU Clinical Trials Directive.[8]

The EMA guidance and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (GCP) primarily address overarching issues related to FTIH trial participant risk identification and mitigation. For instance, they emphasize the need for a careful risk reduction strategy incorporated within standard operating procedures (SOPs). However, these guidelines provide limited details regarding the specific requirements for dedicated clinical trial unit (CTU) facilities. They only highlight the significance of conducting these trials in suitable facilities staffed by well-trained and experienced medical personnel.[6]

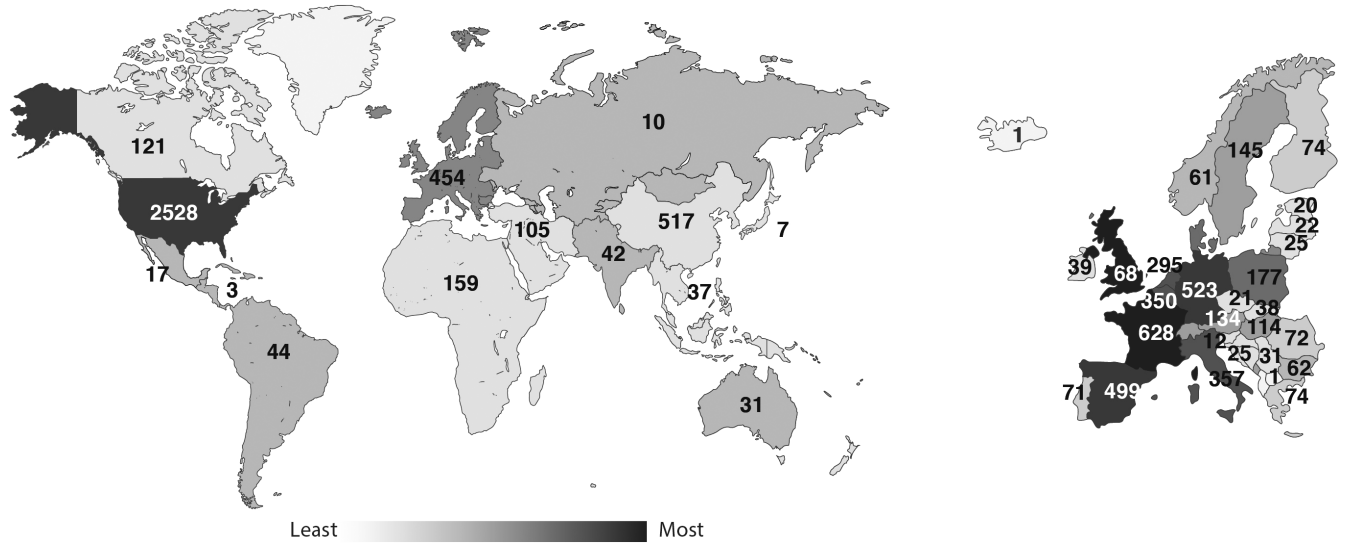

FIGURE 1 Schematic map of the early phase I trials registered on clinicaltrials.gov.[7] (adapted from clinicaltrials.gov).

THE SIGNIFICANCE OF ACADEMIC PHASE I UNITS

Different types of phase I CTUs coexist in the European continent that can be classified as academic or private, depending on their nature. Academic CTUs are managed by academic investigators and tend to be integrated within a hospital or university facilities. Academic FTIH units are diverse, and in many cases are led by clinical pharmacology departments specialized in a therapeutic area or a specific type of phase I trial. This allows for the development costs to be considerably lower than non-academic phase I units. Conversely, private units are primarily associated with pharmaceutical companies or contract research organizations (CROs).[9] An analysis conducted on clinicaltrials.gov data reveals that 62.4% of the FTIH trials conducted in Europe are industry-sponsored.[10] Dunlop et al. studied the participation of academic sites in company-sponsored clinical trials and concluded that a decline had been seen in recent years.[11]

In some countries, prior to performing any activity, CTUs must be accredited as a phase I unit by the local Regulatory Authority.[12] In order to obtain said accreditation, the Regulatory Authority performs a checklist of the minimum required equipment and facilities and reviews the CTU's SOPs. For academic CTUs this accreditation is sufficient to perform academic research-based FTIH trials, providing these units with experience in early phase I trials for advanced therapies. In addition, this accreditation allows these CTUs to perform safety, pharmacokinetics, and pharmacodynamics evaluations and industry-sponsored FTIH trials within the realm of oncology as the majority of these clinical trials occur within academic units or National Health Service (NHS) hospitals due to the profile of oncology patients. However, current accreditations alone do not meet the criteria considered sufficient to host a FTIH by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and Associated Partners who conduct FTIH trials in healthy volunteers as part of developing the molecule for regulatory filing. Currently, there are no international requirements or accreditation processes for phase I units to conduct FTIH, hampering the number of academic CTUs that can be adapted to perform these trials according to regulatory industry standards.

To regain the participation of academic CTUs in company-sponsored FTIH trials, EFPIA partners and other partners involved in clinical development must validate them. Therefore, there is a need for them to define an assumable set of minimum qualification criteria that these units must meet to perform FTIH trials to the appropriate standards.

Public–private collaboration in the development of antituberculosis drugs: ERA4TB

The European Regime Accelerator for Tuberculosis (ERA4TB) is an innovative medicines initiative (IMI) aimed at building and consolidating a global mixed network of company and academic partners across Europe with the ambition of creating a novel world-class platform for the effective acceleration of new anti-tuberculosis (TB) drugs and regimens. This initiative is a public–private partnership funded by the European Commission, aimed at fostering collaboration between academic and

pharmaceutical partners to accomplish the established goals and to tune up the academic units for the development of anti-tuberculosis drugs.[13] This new platform also intends to integrate, maintain, and further advance the drug development processes and tools needed for the effective acceleration of anti-TB drug combinations.[14]

The leading pharmaceutical companies and Associated Partners participating in ERA4TB will share a significant number of advanced lead anti-TB compounds with academic partners and small and medium-size enterprises (SMEs) with two specific goals: first, to mature the ERA4TB TB platform as a sustainable and efficient resource for the future with a global purpose of fighting TB; and second, to identify promising new compounds to be quickly progressed into phase I clinical trials. To achieve these goals, ERA4TB has laid down a structure of highly interconnected work packages (WPs) to ensure the execution of the progression pipeline.[14]

ERA4TB WP7 is responsible for the development of FTIH trials, from their design, to their implementation, execution, and completion.[14] The Consortium integrates six phase I CTUs across Europe, five of them academic and one private. A feasibility tool has been elaborated in collaboration with the academic units, EFPIA, and Associated Partners to encompass the essential prerequisites for FTIH units, particularly academic CTUs. The feasibility has become a tool to validate the Consortium's CTUs with the aim of promoting the participation of academic CTUs in industry-sponsored and regulatory standard FTIH trials.

DEVELOPMENT OF A FEASIBILITY TOOL FOR ACADEMIC PHASE I UNITS

In consonance with the objectives of the European initiative ERA4TB, a feasibility tool aligned with the principles of ICH GCP and recommendations from the EMA was collaboratively developed by Servicio Madrileño de Salud (SERMAS), GlaxoSmithKline (GSK), Janssen, Global Alliance for TB Drug Development (TB Alliance), Evotec International GmbH, and the Bill and Melinda Gates Foundation.

The feasibility tool embodies a comprehensive framework encompassing two pivotal components: the feasibility form and the set of minimum prerequisites that academic units can strive to meet. These criteria have been the result of a consensus forged among academia, EFPIA, and Associated Partners.

The feasibility form is divided into nine sections, each collecting information on a critical requirement for the performance of FTIH trials. Section 1 (experience in phase I trials) deals with the number of trials conducted by the unit in the previous years and their description (e.g., length of participant stay and food requirements). Section 2 (phase I CTU establishment) focuses on the characteristics of the unit (e.g., number of beds, proximity to emergency care, equipment available, and archiving facilities). Section 3 (participant recruitment and management) considers participant recruitment strategies. Section 4 (pharmacy capabilities) establishes the characteristics of the FTIH pharmacy (e.g., location, activities, ability to import API, and experience with import licenses). Section 5 (clinical trials unit activities and experience) gathers information on which clinical trial services can be offered by the unit and which activities need outsourcing. Section 6 (quality assurance) covers audits and inspections, accreditations, and SOPs. Section 7 (system management) documents systems and software used for clinical trial activities (e.g., electronic case report form [eCRF], electronic trial master file [eTMF], and clinical trial management system [CTMS]). Section 8 (project management) focuses on the functions and responsibilities of project managers. Section 9 (regulatory authority and ethics committee management) articulates submission and approval processes.

The complete feasibility form is available as an attachment to this article (Table S1).

Table 1 provides the compilation of the minimal criteria that a CTU must satisfy to qualify for the execution of a FTIH trial, in strict adherence to the stringent standards imposed by both regulatory authorities and the pharmaceutical industry.

The minimal criteria outlined within each section of the feasibility form are meticulously elucidated. To qualify, a CTU must demonstrate a comprehensive track record encompassing phase I trials, including those of extended duration and trials necessitating specialized dietary provisions. Additionally, the CTU should hold accreditation to conduct phase I clinical trials, if such accreditation is conferred by the National Health Authority. In order to comply with GCP regulations, the CTU needs to have the necessary equipment: to have direct access to a critical care unit (within 2 minutes) and to have an intensive care physician on call available 24 hours. To ensure participant recruitment, the CTU needs to have access to healthy volunteers through an active registry or any other method. A dedicated pharmacy is required to receive the investigational medicinal product dossier (IMPD) and prepare the investigational medicinal product (IMP). It is also required for the CTU to be able to perform essential clinical trial activities (e.g., writing study documents, submitting study documents to regulatory authorities and ethics committees, performing monitoring activities, and having

TABLE 1 Sections in the feasibility questionnaire and minimum criteria per section.

1. Experience in phase I trials	A minimum of 5 years' experience, encompassing the execution of no fewer than 10 phase I trials
	Experience in prolonged patient stays, with "long-term stay" defined as exceeding a duration of 2 weeks (five clinical trials of prolonged stay in the past 3 years)
	Capability to conduct cardiac monitoring and electronically archive electrocardiogram (ECG) data
	To have experience in accommodating dietary specifications, at least for one first-time-in-human (FTIH) trial in the last 3 years
	To have an official accreditation as a phase I unit (if applicable according to national legislation)
2. Establishment of the phase I clinical research unit (CRU)	Immediate access to an intensive care unit within a 2-minute timeframe, available around the clock (24/7)
	To have a minimum of 8–12 beds within a single, unified location
	To have implemented an infectious disease protocol, including COVID-19
	Regulated entry to the unit
	Possess an adequate staffing complement for the execution of clinical trials: 1 Project Manager and back-up 1 Principal Investigator 1 Principal Investigator delegate At least 2 sub-investigators 1 nursing team coordinator 1 medical team coordinator Number of doctors and nurses will depend on study design 1 quality control
	To maintain, at least, the following equipment available: emergency trolley, defibrillator, intubation equipment, temperature monitoring equipment, suction equipment, 12-lead ECG, blood pressure/heart rate monitors, scales, synchronized clocks, centrifuges, fridge, freezer, back-up generators, alarm system and Holter monitors
3. Participant recruitment and management	To possess the capability to recruit healthy volunteers
4. Pharmacy capabilities	Experience preparing investigational medicinal product (IMP), at least for 1 FTIH trial in the last 3 years
	Be located in close proximity to the unit
	Limited entry
	Capable of importing active pharmaceutical ingredients (API)
	Availability of a qualified person (QP) for the release of IMP
	Capability to handle storage, labeling, and (un)blinding processes
	Capacity to perform pharmaceutical product accountability
5. Clinical trials unit (CTU) activities and experience	Demonstrated participation of the principal investigator (PI) in a minimum of one FTIH trial in the last 3 years
	Experience in the development of protocols, informed consent forms (ICF), and investigational medicinal product dossiers (IMPD). Experience providing support on protocol, ICF, and IMPD to industry and academia
	Experience in the submission process to regulatory authorities and ethics committees. At least have submitted for evaluation two early-phase studies over the last 3 years. Experience providing support on regulatory and submission to the industry and academia
	Possess the capacity to either conduct internal independent monitoring activities or external contracts for the same purpose
	Have protocols for vendor management
	Documented procedures for dose escalation
	Access to both bioanalytical and pharmacokinetic data analysis support, substantiated by laboratory experience, certificates, and a minimum of one successful audit
	Presence of a qualified PI and/or medical director, with (co-)authorship in at least two scientific publications on completed FTIH trials in peer-reviewed journals over the last 5 years and track record of participation in at least two FTIH trials
	Accessibility to statistical support, with consideration for adaptive designs when necessary

(Continues)

TABLE 1 (Continued)

6. Quality assurance	At least one external audit conducted within the past 2 years, which did not yield any critical findings
	To have own standard operating procedures (SOPs) written in English, encompassing protocols for risk assessment and risk mitigation
	To have access to an independent quality assurance (QA) group
7. System management	Systems and software that have been validated and adhere to compliance standards
8. Project management	Capability to designate a project manager for a particular study
	Prior experience in early-stage clinical trials. At least have managed two early-phase studies within the last 3 years
9. Regulatory authority and ethics committee/ institutional review board (IRB) management	Independent ethics committee in accordance with both International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (GCP) and local regulations

validated systems and software, or being able to outsource them).

IMPACT

The objective behind the creation of the standardized feasibility tool was to define the essential criteria necessary for academic CTUs to align with both regulatory and industry benchmarks. This tool's overarching aim is to facilitate the validation process of CTUs within the ERA4TB Consortium, a task jointly undertaken by the participating EFPIA partners. Furthermore, it is envisioned that this tool will find utility beyond the confines of the project, serving as a valuable resource for a broader spectrum of applications.

Value to the development of FTIH trials

The feasibility tool developed has contributed to the initial two phases in the validation of CTUs for the development of FTIH trials.

The first step in the validation of a CTU entails gathering information on the unit in relation to the essential aspects of FTIH trials. The feasibility form developed by ERA4TB's WP7 members was designed to elicit the requisite details on the units.

The second step involves cross-referencing the gathered data with a predetermined set of essential prerequisites. The feasibility tool also includes a minimal set of criteria for academic CTUs, which have been collectively established and accepted by the academic partners, EFPIA, and Associated Partners.

Subsequent steps in the selection and validations of CTUs for the conduct of FTIH trials depend on the specific requisites established by each sponsor.

Value to the Academic Phase I Units

The compiled list of requirements serves as the cornerstone for the validation of academic CTUs as FTIH units under the perspective of EFPIA and Associated Partners. This list is a valuable instrument for academic units, enabling them to align their resources for the development of FTIH trials and successfully pass the assessment visit of the companies. Validation as a FTIH CTU entails the demonstration of four key aspects. First, it ensures compliance with regulations and standards, including GCP. Second, it demonstrates compliance with requirements set by SERMAS, EFPIA partners, and Associated Partners. Third, it proves that the unit is staffed with expert personnel. Lastly, it establishes the unit is competent in the development of FTIH trials sponsored by companies. Furthermore, although initially designed for conducting FTIH trials in volunteers, which is the central focus of the ERA4TB project, this feasibility tool could also be used to validate CTUs that meet these requirements for conducting various other phase I studies. These could include proof of concept (PoC), interaction studies, as well as pharmacokinetics and pharmacodynamics (PK-PD) evaluations.

Value to the EFPIA and Associated Partners

The minimum criteria integrated into the feasibility tool are in accordance with other established requirement

frameworks, notably ICH GCP, although they possess a distinct emphasis and depth of specificity. Consequently, the tool has harmonized the criteria outlined by EFPIA partners, Associated Partners, and academic collaborators within WP7 with the stipulations of GCP and EMA. This tool offers a straightforward and structured means of validating academic CTUs for the execution of FTIH trials involving innovative molecules developed by the industry.

Value to the public–private partnership

The collaboration has favored the flow of knowledge and information among parties and has led to an understanding of the specific criteria each partner looks for in FTIH units. Furthermore, the development of the feasibility tool constitutes the first step towards a public–private partnership favoring the participation of academic sites in industry-sponsored FTIH trials. Public–private partnerships are seen as an innovative method to collaboratively reach the desired outcome.

Many academic institutions in the public sector have established relationships with private companies for specific research activities such as development of new drugs, therapies, and treatments.[15] Moreover, the European-funded IMI initiative promotes public–private partnerships as part of its framework. However, despite the current popularity of this type of partnership, no validation method has been published to promote the feasibility of academic units in FTIH industry-sponsored trials. This collaboration has also contributed towards the stimulation of a new era of research and new funding incentives. The impact is significant for academic research in terms of new knowledge creation, better understanding of the disease, implementation of assays and techniques already validated and sourced from the Consortium members or collaborating partners, potential for new techniques and assay validation, access to a wealth of data generated in diverse studies, and better integration of research efforts and synergy exploitation.

Value to ERA4TB

The introduction of the certification procedure within ERA4TB resulted in the accreditation of the five academic CTUs, which are now prepared to carry out FTIH trials as part of the Consortium. This accreditation was granted by the EFPIA and Associated Partners for the purpose of facilitating the development of FTIH trials sponsored by companies.

The feasibility tool has streamlined the completion of the initial two steps in the CTU validation process. Further verification of the provided information was conducted through an on-site assessment carried out by an EFPIA partner. During the visit, the aspects outlined in the feasibility form were reviewed against the established minimum criteria. Subsequent to the assessment, an evaluator generated a comprehensive report outlining the specific aspects of each facility in accordance with the criteria, and this report was made available to all Consortium partners.

In cases where the report indicates the need for adjustments, the units can be granted access to it, allowing them to address any potential shortcomings in anticipation of a second evaluation. In one instance, it was necessary to adapt one of the CTU's SOPs to align with the minimum requirements, thus ensuring validation by the industry. A favorable report outcome leads to the validation of the CTUs. Furthermore, periodic reviews are contemplated to confirm ongoing compliance with these requirements.

CONCLUSIONS

The collaborative endeavor between the public and private sectors within the project has culminated in the development of a feasibility tool tailored for the execution of FTIH trials by academic CTUs, meticulously aligned with both regulatory mandates and industry benchmarks. This pioneering certification process, crafted within the framework of the ERA4TB project, marks the first mechanism aimed at accrediting academic CTUs for undertaking FTIH trials sponsored by corporate entities. Notably, this process has resulted in the successful validation of five academic CTUs within the ERA4TB Consortium, a recognition duly acknowledged by EFPIA and Associated Partners.

The ultimate aspiration of this initiative is to evolve into an openly accessible set of criteria, poised to be utilized by any clinical trial sponsor seeking to ensure the highest standards of FTIH trial execution. Additionally, CTUs themselves may employ it as a formal checklist to tailor their units in accordance with these criteria.

This symbiotic collaboration between the public and private sectors has yielded mutual benefits. The validation of academic CTUs as FTIH units by private corporations empowers these academic institutions to conduct such trials in adherence to the most exacting industry standards, thus meeting and even exceeding industry expectations. Consequently, this paradigm shift can potentially result in an augmented involvement and substantial contributions from proficient academic CTU in the realm of company-sponsored FTIH trials.[9]

ACKNOWLEDGMENTS

The team acknowledges the editors and reviewers of this article.

FUNDING INFORMATION

The project leading to this publication has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No. 853989. The JU receives support from the European Union's Horizon 2020 Research and Innovation Programme and EFPIA and Global Alliance for TB Drug Development Non-Profit Organization, the Bill & Melinda Gates Foundation, and the University of Dundee.

CONFLICT OF INTEREST STATEMENT

The authors declared no competing interests for this work.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Moraga P, Prieto P, Conradie A, et al. Academia and industry agreement on a feasibility tool for first-time-in-human clinical trial units. *Clin Transl Sci*. 2023;16:2421-2428. doi:10.1111/cts.13655