IHI Call Days | Call 9

Advancing Clinical Research in Europe: Building a Framework to Strengthen Pragmatic Clinical Trials and Accelerate Integrated Product and Service Development with AI-Driven Technologies

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Link to the IHI brokerage platform:

- Proposal sharing tool: https://ihicalldays2024.converve.io/index.php?page=cat_tech&action=detail&params%5Bq%5D=trial&params%5B_filtered%5D=1&params%5Bsort_by%5D=comp_name&params%5Bhtpageparserstring%5D=index&params%5Bevent_id%5D=1&params%5Bid%5D=621&params%5Bshow%5D=tech
- Participant profile: https://ihicalldays2024.converve.io/index.php?page=meet_request_meetings&action=detail&params%5Bq%5D=clininote&params%5Bshow%5D=&params%5Bevent_id%5D=1&params%5Bid%5D=621&params[pers_id]=634

CliniNote

innovative health initiative

Challenges and objectives

We are addressing **Specific Objective 2** and **4** with a particular focus on:

- Clinical trials in Europe face challenges that slow down research due to diverse languages, regulations, and healthcare systems.
- High costs and administrative burdens are particularly tough for academic-led studies competing for funding.
- Cross-border complexity & compliance raises costs, limiting research scope.
- Integrating Real-World Evidence (RWE) is further hindered by inconsistent data standards, limited cross-border data access, and a lack of interoperability.

We aim to introduce a **new framework for Clinical Trials** that will **reduce barriers in planning** and resource allocation while **improving the efficiency of trial execution**. By leveraging innovative technologies, the framework will incorporate Real-World Evidence (Pragmatic Clinical Trials), enabling the reuse of trial outcomes and source data within the European Health Data Space (EHDS).

Your approach to solve the problem

Key areas:

- **Barrier Identification**: We will identify and refine the main obstacles limiting the success of RCTs, engaging with key stakeholders (eg ECRIN under the EMA's patronage). Main focus: planning, initiation, data quality and integrity resulting in simplified and efficient monitoring, faster closure and overall study effectiveness.
- **Framework Development**: We will create an innovative framework, to improve the efficiency and reduce the barriers of traditional non-commercial RCTs using large-AI-model based RCT Simulation and automated data collection.
- **Pilot Implementation**: The framework will be piloted within the selected HCPs under EMA's guidance.
- **Integration with PCTs**: Based on the success of the RCT framework, we will develop a similar approach for PCTs, leveraging real-world data (RWD) collection and EHDS regulations.
- **Data Contribution**: Data from PCTs will contribute to EHDS resources, ensuring reusability.
- **Educational Campaign**: We will launch a comprehensive educational campaign targeting researchers and non-commercial CT sponsors.
- **Free Access to Tools**: The developed framework and tools, including the AI model and CliniNote Assistant (basic versions), will be made freely available (or freemium) to affiliated centers for non-commercial clinical trials over a defined period.

Is your project suitable for IHI?

YES, this project supports the IHI's general objectives by 2030 and overarches goals of development of methodologies for the assessment of safety, health outcomes, or for health-economic evaluation as well as improving health outcomes, fostering public-private collaboration, and advancing a unified, digital health ecosystem across Europe.

- **Increasing Efficiency and Reducing Barriers of Clinical Trials**:
- **Incorporating Real-World Evidence (RWE)**
- **Enhancing Data Reusability and EHDS**
- **Utilizing Innovative Technologies (AI & NLP)**

Our project is addressing T2 (SO2): integrate fragmented health research & innovation efforts bringing together health industry sectors and other stakeholders, focusing on unmet public health needs, to enable the development of tools, data, platforms, technologies & processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users;

Also supporting **T4 (SO4)**: exploit the full potential of digitalisation and data exchange in healthcare;

Outcomes and Impact

Improving efficiency and reducing barriers in clinical trials offers substantial benefits for both patients and the healthcare system.

- A streamlined, AI-powered clinical data capture framework that eases the burden on clinicians while **generating valuable, structured medical data**. **Accelerated clinical research and drug development** through efficient and accessible data-driven insights.
- A collaborative approach that involves industry, healthcare providers, and patient advocates to ensure **ethical development and real-world i**mpact, benefiting all stakeholders.
- Enhanced EU healthcare competitiveness by accelerating research, fostering innovation, and contributing to the European Health Data Space.
- **Direct patient benefits** including improved data accessibility, accelerated treatment development, and enhanced healthcare outcomes.
- **Wider availability of interoperable**, quality data, respecting FAIR principles, **facilitating research and the development of integrated products and services**.

Expertise and resources 1

- **We have:**
  - Initial commitment from an NGO organization comprising over 160 hospitals (access to expertise, clinical data, and the opportunity to conduct pilot studies)
  - A partner (SME) developing predictive models for clinical trial endpoints (access to expertise, technology, and the opportunity to conduct pilot studies)
  - Preliminary interest from a leading technology firm specializing in graphics processing units (GPUs) and artificial intelligence (AI technologies and expertise)
  - Preliminary interest from global pharma company
- **We provide**
  - In-kind contribution – the CliniNote Data Platform to all public and clinical partners and contributors.
  - Our experience from previous projects: Idea4RareCancers, DigiOne_I3, Strong_Aya

Expertise and resources 2

- **We are seeking:**
  - **Industry Partners**: Pharmaceutical companies and Contract Research Organizations (CROs) interested in collaboratively developing a pragmatic clinical trial (PCT) framework and integrated products and services.
  - **Healthcare Providers**: Hospitals and polyclinics with expertise in conducting pan-European clinical trials.
  - **Patient Advocacy Groups**: Organizations committed to ensuring high-quality data is readily available to patients in accordance with FAIR principles and supportive of the secondary use of data within the European Health Data Space (EHDS) framework.
  - **Technology Partners**: Experts in clinical trial technologies, such as electronic case report forms (eCRF) and e-source systems.
  - **Regulatory and Compliance Experts**: Professionals with experience in navigating the regulatory landscape to ensure compliance in clinical trials.