

Internationalization of Clinical Trials in H2020: New opportunities for Clinical Research

Gemelli



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Agenda:

- **European legislation on Clinical Trials: Guidelines and Directives**
- **Clinical Trials in H2020:**
 - What is a Clinical Trial in H2020
 - Challenges and opportunities
 - Budgeting issues: Unit Cost and Subcontracting
 - The SPRINT-T Project - Success case of an interventional European Clinical Trial
- **Opportunities for Italian Institutions: Initiatives supported by the Ministry of Health**
 - Joint Programming Initiatives (JPI)
 - ERA-Net Cofund
 - Coordination and Support Actions
- **Work Programme 2018/2020 “Health, demographic change and well-being”**
 - List of actions that will support Clinical Trials

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Good Clinical Practices have been progressively introduced in Europe through different guidelines and directives, primarily represented by:

- **E6: Good Clinical Practice: Consolidated Guideline 1996**

- **Clinical Trials Directive 2001/20/EC**
 - Main goal: **harmonizing the principles that regulate clinical trials.** The Directive applies to studies from Phase I to Phase IV.
 - In Italy: the Directive has been adopted with the Legislative Decree n° 211 of 2003, establishing that all clinical trials on medicinal products for human use starting from May 2004 on, **should be conducted in adherence with GCP.**

○ GCP Directive 2005/28/EC

- Main goal: laying down principles and detailed guidelines for good clinical practice **as regards investigational medicinal products for human use**, as well as the requirements for authorization of the manufacturing or importation of such products.
- In Italy: The Directive has been adopted with the Ministerial Decree of December 27th, 2007

○ Clinical Trials Regulation (CTR) EU No 536/2014

The legal form of a Regulation will ensure that:

- the **rules** for conducting clinical trials are **identical throughout the EU**, in order to ensure that Member States base themselves on identical rules
- **Increased transparency** as regards clinical trials and their outcomes.

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What is a Clinical Trial in Horizon 2020?

→ “Any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients”.

This includes different types of trials:

- a) Observational studies
- b) Interventional studies
- c) as well as all phases (Phase I – IV).

} In H2020 are all eligible for funding

Challenges and Opportunities:

The implementation of clinical trials

- ✓ *facilitates the process to reach sufficient patient numbers* (especially in the case of rare diseases and stratified treatment groups)
- ✓ *speeds up recruitment rates*
- ✓ *contributes to consolidate expertise*

Budgeting issues

Introduction of **Unit Costs** and **Subcontracting** facilitated the budget planning and financial aspects of trial implementation

→ both designed to face challenges that are typical for clinical trials such as:

the possible necessity for adaptation of (the number of) recruiting centers during the project lifetime, dealing with drop-outs, or competing studies

Unit Cost:

- a) Fixed reimbursement amount
 - b) For each study subject enrolled
 - c) In a given centre
- ✓ **Ex-ante acceptance of unit costs** = No need for time sheets and detailed tracking of resources used.
 - ✓ Simple and transparent method for calculating, reimbursing and auditing costs of clinical studies.

Subcontracting:

Clinical centers that enroll, treat or follow patients can be included as a subcontractor



The SPRINT-T Project

Success case of an interventional European Clinical Trial

- **IMI funded project**
- **First non competitive interventional European clinical trial in frail sarcopenic older patients using physical activity as benchmark for future studies with investigational drugs.**
- **Objectives of the project** → To validate an interventional paradigm for identifying at-risk individuals living in the community and evaluate innovative therapeutic interventions against physical frailty and mobility disability.
- **Five-year project**
- **Collaboration between sixteen research institutions in the geriatric field across Europe**

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The Italian Ministry of Health supports JPIs, ERA-Net Cofund and CSA

- These are structured and strategic process whereby Member States agree, on a voluntary basis and in a partnership approach, on common visions and Strategic Research Agendas (SRA) to address major societal challenges.
- All these initiatives can fund Clinical Trials

➤ **Healthy Ageing** → JPI MYBL (More Years Better Lives) - ERANET J-AGE:

This initiative seeks to enhance coordination and collaboration between European and national research programmes related to demographic change.

➤ **Diet and Nutrition** → JPI HDHL (JPI on A Healthy Diet for a Healthy Life):

This initiative aims to bring major benefits to particular sector of public and societal life such as Health and Nutrition.

➤ **Neurosciences** → JPND (Joint Programming on Neurodegenerative Disease) - JPCoFund ERANET NEURON 2

JPND is the largest global research initiative aimed at tackling the challenge of neurodegenerative diseases.

- **Oncology** → ERANET TRANSCAN2.
Initiative that fosters the collaboration in translational cancer research
- **Rare Diseases** → ERANET E-Rare - in accordance with the Strategic Initiative IRDiRC (International Rare Diseases Research Consortium)
Enhance the cooperation between European scientists working on rare diseases and thus reducing the fragmentation of research in this field.
- **Infectious Diseases** → JPI AMR (AntiMicrobial Resistance) - ERANET Infect-ERA
Collaborative action for filling knowledge gaps on antimicrobial resistance
- **System Medicine** → CSA CASyM – ERANET ERACoSysMed
Enhance the implementation of systems biology approaches in both clinical research and medical practice

- **Personalized Medicine** → ICPeMed (The International Consortium for Personalised Medicine)
Initiative that aims to coordinate and foster research to develop and evaluate personalised medicine approaches
- **Nanomedicine** → ERANET Euronanomed III
Supports multidisciplinary and translational research and innovation projects that cover: Regenerative medicine, Diagnostics and Targeted delivery systems.
- **EU-CELAC countries** → ERA-LAC – ERANET ERANet-LAC
Initiative between the European Union (EU) and the Community of Latin American and Caribbean States (CELAC) It aims to strengthen the bi-regional partnership in Science, Technology and Innovation.
- **EU-Sub Saharan countries** → EDCTP2 (European and Developing Countries Clinical Trials Partnership)
Initiative that supports clinical trials on poverty-related infectious diseases, as well as capacity for conducting clinical trials and related research in sub-Saharan Africa.

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Call 1. "Better Health and care, economic growth and sustainable health systems"

1.1 Personalised medicine

SC1-BHC-01-2019 (ex-1): Understanding causative mechanisms in co-morbidities

SC1-BHC-02-2019 (ex-4): Systems approaches for the discovery of combinatorial therapies

SC1-BHC-03-2018 (ex-5): Exploiting research results and potential of the human microbiome for personalised prediction and prevention of disease

SC1-BHC-04-2018 (ex-10): Rare Disease Joint Programme Co-Fund

SC1-HCO-01-2018-2019-2020 (ex-CSA1): Actions in support of the International Consortium for Personalised Medicine

SC1-HCO-02-2018 (ex-CSA9): Data integration and data-driven in-silico models for enabling personalised medicine - a European standardization framework

SC1-HCO-04-2018 (ex-NEW CSA12): ERA-NET to support the Joint Programming in Neurodegenerative Diseases strategic plan (JPND)

1.2 Innovative health and care industries

SC1-BHC-07-2019 (ex-3): Regenerative medicine: from new insights to new applications

1.3 Infectious diseases and improving global health

SC1-BHC-14-2019 (ex-11): Stratified host-directed approaches to improve prevention and/or treatment of infectious diseases

SC1-BHC-15-2018 (ex-12): New anti-infective agents for prevention and/or treatment of neglected infectious diseases (NID)

SC1-BHC-18-2019 (ex-18bis): EU-CELAC collaboration for research on non-communicable diseases

1.4. Innovative health and care systems - Integration of care

SC1-BHC-23-2018 (ex-13): Novel patient-centred approaches for survivorship, palliation and end-of-life care

*Thank you
for your attention*