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NEWSFLASH

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ERA4Health Partnership

Special issue concerning Investigator-Initiated Clinical Studies (IICS)

Interview with Jacques Demotes, Director General of Ecrin (European Clinical Research Infrastructure Network)

1. What do we mean when we say IICS?

Investigator Initiated Clinical Studies (IICS) are clinical studies designed and managed by academic investigators and funded by public or charity funds. These are in contrast to clinical studies designed and sponsored by the health industry with a marketing authorization perspective.

2. hat are the different types of studies that we typically associate with IICS?

IICS include observational studies (cohorts), and interventional studies (clinical trials). The objective of these trials may be :

- academic innovation, for instance developing innovative biotherapies in areas out of the scope of industry, because the disease is very rare, or because the technology is still under development (gene editing, cell therapy, regenerative medicine). In Europe, academic innovation accounts for a limited subset of IICS.
- drug repurposing, exploring new indications for health products already approved in other conditions, based on common features in the mechanism of disease. This is particularly relevant in cancer, or in rare diseases.
- comparative effectiveness or treatment optimization trials, using approved health products within their licensed indication, to determine the best treatment option for a given disease or for a subgroup of patients, or to test various treatment regimens or combinations to maximize efficacy and safety.

3. Why is it important to fund and support the IICS?

IICS need public funding because they address questions relevant to public health, and not industry development. IICS are key instruments to improve the quality and efficacy of healthcare, while containing its costs. Academic innovation brings therapeutic solutions in areas uncovered by the market forces, treatment repurposing takes advantage of already developed compounds, and comparative effectiveness / optimization trials generate robust evidence on questions addressed by HTA bodies on the efficacy, safety and cost-effectiveness of treatments, to make appropriate decisions on guidance and reimbursement.

4. Why is there a need for a dedicated mechanism for funding multinational IICS?

While the majority of industry-sponsored trials in Europe are multinational, only a small percentage of IICS are (and when they are, the number of countries involved is low). This is indicative of substantial obstacles for universities and hospitals to act as the single sponsor in Europe, and also of a lack of appropriate funding mechanisms. Currently, most of the public funding for multinational IICS comes from the central budget of the EU DG-RTD (Horizon 2020, Horizon Europe), represents a limited budget. A few trials are supported by cross-border public funding from the few countries where funding bodies are allowed to spend money outside the country. However, this remains insufficient to fund a substantial amount of large, multi-country IICS.

5. What is the advantage of a multinational IICS?

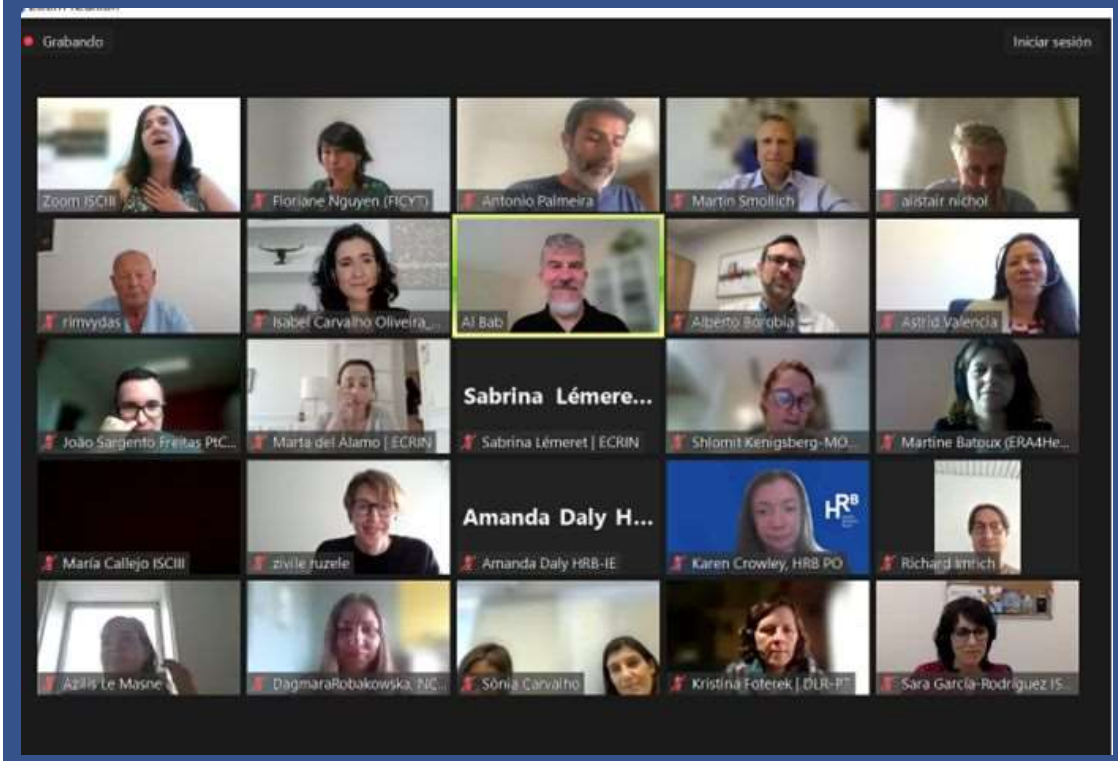
Joining forces through the design, planning and conduct of multinational IICS is necessary to rapidly reach the recruitment target and lead to statistically powered results. In addition,other advantages of multinational trials are accessing medical expertise throughout Europe, unlocking the scientific potential, using the highest methodological standards and common tools, using pan-European investigation networks and pan-European clinical study infrastructures, addressing the diversity of

EU patients and health systems thus increasing the generalizability of the results, avoiding the duplication of trials addressing in parallel the same questionand sharing the cost of the trials.

6. How is ERA4Health supporting multinational IICS?

ERA4Health funds multinational IICS through the combination of national funds, plus an EU Co-fund. The national funds will be used to cover the cost of investigation (paid to recruiting sites in the hospitals) in each of the participating countries, without any cross-border transfer of money. In addition, the EU Co-fund will be used to support the trial management activities, conducted by the study sponsor, as they require cross-border funding (site monitoring, vigilance, data management, regulatory and ethical approvals etc). This mechanism will avoid cross-border use of funds originating from national funding bodies – only the EU Co-fund will cross national boundaries. Moreover, ERA4Health has identified bottlenecks and challenges to multinational studies and will raise the quality of supported trials through a selection based on scientific excellence, public health relevance, and trial management capacity, together with a close monitoring of the trial conduct. This mechanism has the potential to spread to other EU-Partnerships, and to substantially increase the amount of IICS run as multinational studies in Europe, taking advantage of Europe's population size, of the quality of its healthcare systems and of its scientific excellence to boost Europe' competitiveness in clinical research.

Workshop: Boosting European Health Research: ERA4Health's Initiative for Enhanced Funding and Collaboration.



On Wednesday 3 July, our consortium held a workshop to refine the topic of the ERA4Health Pilot Call on Investigator-Initiated Clinical Studies (IICS).
This partnership provides an opportunity to increase funding for European trans-national collaborative research by creating a funding body for joint programming in priority areas that address European public health needs. Multinational IICS play a key role in addressing societal issues that often go unnoticed by industry players, highlighting their high societal value. However, despite their importance, these studies often face challenges due to the lack of optimal funding mechanisms.
To address this issue, the ERA4Health partnership has developed a framework and plans to launch its first call dedicated to IICS in November this year. The aim of this workshop was to refine the call topic and discuss specific issues with experts and funding agencies in order to encourage and enable transnational collaboration between clinical and public health research.

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Communication contact

Jessy Claeys
Flanders Research Institute for Agriculture, Fisheries and Food (ILVO, Belgium)
ERA4Health.communication@ilvo.vlaanderen.be

Thank you for showing interest in this Partnership. We greatly value your support and participation. If you have any questions, comments, or research insights you would like to share, we encourage you to reach out.

Sincerely, ERA4Health

Reach out

If your organisation is interested in being involved in the ERA4Health network and activities, please contact Cristina Nieto,

era4health@isciii.es

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