

Shifting the Paradigm for Patient Recruitment: Needs, Options and Challenges for Trial Matching Solutions

Your voice matters!

13 June at 14:00 - 19:00 CEST (Virtual Open Consultation)

Multi-stakeholder Open Consultation

INTRODUCTION

The current approach to recruitment of patients into clinical trials is complex, fragmented, competitive and unreliable, leading to delays in clinical trial performance and thus availability of new treatments to patients. Only a very small percentage of patients are interested in joining a clinical trial, also because a proactive search for clinical trials and thus innovative treatment options are much too difficult for most patients and too cumbersome for their treating physicians. Sources of information on available trials are scattered, incomplete and often outdated. Patients are concerned about entering personal health data into databases and the fate of their information, especially when such databases are owned by commercial organisations.

To fundamentally change the situation, multi-stakeholder collaboration is required including trial sponsors, clinical investigators, patients, treating physicians and neutral platform providers that enable sharing and access to selected, patient-owned data in a secure environment. When the involved processes are patient-friendly and trial offerings fit patients' expectations, a larger percentage of patients are likely to become interested and able to join clinical trials, and this increased patient pool might help speed up the recruitment process. Suitable pre-screening options can reduce the workload for investigator sites and enhance their interest in recruiting patients through such a matchmaking tool.

The clinical trial landscape is developing very rapidly. New technologies and new forms of collaboration between different stakeholders enable innovative solutions. In the IMI public-private partnership project, PharmaLedger is introducing blockchain technology into medicines development and healthcare through trans-sector, multi-stakeholder collaboration for patient-relevant solutions. The opportunities of this constellation could enable a paradigm shift in the recruitment process for clinical trials. The needs, opportunities, and challenges in concretely establishing such a patient-centric, joint recruitment environment will be discussed in this multi-stakeholder workshop.



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AGENDA

14:00 **Welcome and Introduction**

Daniel Fritz, Novartis
Valentina Strammiello, EPF
Ingrid Klingmann, EFGCP

SESSION 1 **Needs, options and challenges for a suitable trial matching tool**

Chair: Ingrid Klingmann, EFGCP

14:05 **The current stage of patient recruitment tools**

Speaker: Natalia Sofia, MSD





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- 14:20** **The patient Discussion: What would be required to find a suitable trial more easily?**
Moderator: Hannes Jarke, EPF
Speaker: Mary-Lynne Van Poelgeest-Pomfret, Vice-President EFGCP
Mitchell Silva, Esperity & Patient Centrics
Dominique Hamerlijnc, EUPATI fellow
Q&A
- 14:40** **Ethical aspects of a Trial Matching Solution facilitating patient recruitment into clinical trials**
Speaker: Hugh Davies, Oxford Research Ethics Committee
Q&A
- 15:00** **The investigator view: What are requirements for a suitable match-making solution?**
Speaker: Speaker invited
Q&A
- 15:20** **The treating physician view: Role, benefits and risks of searching a trial for my patient through a matchmaking tool**
Speaker: Silvano Berio, Cardiologist
Q&A
- 15:40** **Break**
- 15:55** **The industry view: How could collaboration between sponsors work for mutual benefit?**
Speaker: Tom Giannaris, Bayer
Q&A
- 16:15** **The lawyer view: Can blockchain offer more transparency and patient autonomy over personal data in the context of clinical trial recruitment?**
Speaker: Halid Kayhan, KU Leuven
Q&A
- 16:35** **Enhanced cross-border patient recruitment through a trial matching tool: Consequent challenges for patients and investigators to overcome?**
Speaker: Teodora Lalova-Spinks, KU Leuven
Q&A
- 16:55** **Progress and challenges of existing trial matching solutions?**
Speaker: Caglar Demirbag, MassiveBio
Q&A
- 17:25** **Bio Break**





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SESSION 2 Roundtable and Open Forum Discussion

Moderator: Steven Bourke, PersonalPulse

17:35 Introduction: How the PharmaLedger eRecruitment Use Case addresses multi-stakeholder needs

Speakers: Natalia Sofia, MSD

João Paulo Luís, PDMFC

Panel and Open Forum Discussion:

What are success factors and hurdles for a trial matching tool across indications for industry, academia and publicly funded trials?

To what degree could the multi-stakeholder PharmaLedger solution become a “game changer”? Which additional elements would need to be solved?

Hannes Jarke (EPF), René Kronenburg (Abbvie), Stephen Leiper (Onorach), Daniel Fritz (Novartis), Xenia Beltran (PharmaLedger Project Coordinator), Caglar Demirbag (Massive Bio), Dominique Hamerlijnc (EUPATI Fellow)

Voting session to collect participants' opinion per stakeholder group

18:50 Concluding remarks

Ingrid Klingmann, EFGCP

19:00 End of the Workshop

ABOUT PHARMALEDGER

Sponsored by the Innovative Medicines Initiative (IMI) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) under the Horizon 2020 programme, PharmaLedger is a 36-month project that brings together 12 global pharmaceutical companies and 17 public and private entities; including technical, legal, regulatory, academia, research organizations and patient representative organizations.



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