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Sous le haut patronage de  
Monsieur Emmanuel Macron,  
Président de la République

# Next generation of clinical research

## AI, in silico and external arm : time to make them real

**June 24, 2024**

10.00 am	Welcoming session
10.15 am	Back to the needs
11.05 am	External arm or hybrid: moving forward 3.0 clinical research ? Are patients affected by slowly progressing diseases condemned to remain without treatment ?
12.15 am	For an ambitious regulation in line with evolution of health products and technologies
12.35 am	Keynote - Is there a pilot in the rocket ?
2.30 pm	Afternoon opening
2.40 pm	Artificial intelligence, diagnosis, prediction, organization of care: how to move forward a personalized medicine - optimized healthcare system ? Digital Medical Devices: Where do we stand in their assessment and what healthtech stakeholders need to know?
3.40 pm	Practical session : Emulated or simulated Practical session : IA to increase and optimize
4.50 pm	Time to move on
5.40	Keynote – Witness of the day
6.00 pm	Wrap up and conclusion of the day



**CHU de Lille – Institut Gernez Rieux**  
2 rue du Dr Schweitzer, Lille





# Next generation of clinical research

## AI, in silico and external arm : time to make them real

### Welcoming session

10.00-10.15 am - AMPHI A

Frédéric Boiron, Director of CHU Lille

Lise Alter, General Manager Of The French Health Innovation Agency

### Back to the needs

10.15-11.00 am – AMPHI A

**Moderator** Alexis Génin (Brain&Mind)

**Speakers** François Lamy (AFM Telethon), David Devos (CHU Lille), Patrick Meshaka (Novartis)

Most “agile” methodologies for clinical research exist since decades and still are rarely used. What key cultural and technical factors are currently preventing their implementation (and how could this change)?

### External arm or hybrid: moving forward 3.0 clinical research ?

11.05–12.10pm – AMPHI A

**Moderator** David Perol (Unicancer)

**Speakers** Remy Choquet (Roche), Louise Baschet (Horiana), Jean Louis Fraysse (BOTDesign), Thomas Filleron, (Oncopole Toulouse) Valérie Denux (ANSM)

Will ultra-rare orphan patients remain without any treatments? How hybrid or external control arms can contribute to generate clinical evidence in ultra-rare/pediatric diseases or fragile populations?

### Are patients affected by slowly progressing diseases condemned to remain without treatment ?

11.05–12.10pm – AMPHI B

**Moderator** Marc Bonneville (ARIIS)

**Speakers** Cecile Ollivier (C-Path), Emmanuel Pham (Novadiscovery), Véronique Briquet-Laugier (Lab'FondaMental), Werner Rein (Theranexus), Gérard Raymond (France AssoSanté)

In which extent does Ph3 RCT find their limits for slowly progressing diseases? How can you demonstrate efficacy with non-subjective endpoints when you are investigating a disease that lasts more than 10 years? Are simulation and/or digital endpoints useful? Robust?



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### **AI, in silico and external arm : time to make them real**

**For an ambitious regulation in line with evolution of health products and technologies**

12.15 – 12.35 am – AMPHI A

Alexandre de la Volpillière (Deputy Director of ANSM)

**Is there a pilot in the rocket ?**

12.35 – 1.10pm – AMPHI A

Isabelle Rongier, Deputy Technical Director Ariane Group

## Lunch break

**Afternoon opening**

2.30-2.40 pm - AMPHI A

Vincent Diebolt – Director for the French Clinical Research Infrastructure Network

**Artificial intelligence, diagnosis, prediction, organization of care: how to move forward a personalized medicine / optimized healthcare system?**

**Moderator** Stéphanie Allassonnière (PR[AI]RIE)

2.40 – 3.35pm – AMPHI A

**Speakers**

Thierry Marchal (Ansys), Corinne Collignon (HAS), Vincent Sobanski (Professor Lille University, University Institute of France), Tala Fakhouri (FDA)

Several AI based decision support systems are now already on the market. The emergence of digital twins and artificial data are opening new possibilities. In this panel, we will discuss the opportunities these new technologies are offering. At the same time, regulatory measures now need to evolve to take into account these developments. The FDA has proposed several guidelines for external-control arms and AI based algorithms. We will now discuss on the next steps we all need to take to accelerate innovation



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#### **Digital Medical Devices: Where do we stand in their assessment and what healthtech stakeholders need to know?**

3.40 – 4.35pm – AMPHI A

**Moderator** Line Farah (DNS, Ministry of Health)

**Speakers** Louisa Stuwe (DNS), Jerome Fabiano (EIT Health), Corinne Collignon (HAS), Sarah Zohar (INRIA-INSERM), Joris Giai (Tech4health), Stéphane Tholander (Agora Health)

The rapid evolution of digital medical devices, encompassing everything from wearable health monitors to AI-powered diagnostic tools, presents a new frontier in healthcare. This panel discussion aims to explore the current landscape of digital medical device assessment, addressing both the regulatory frameworks and the practical challenges faced by developers and healthcare providers.

This roundtable will not only delve into the current state of digital medical device assessment but also equip attendees with the knowledge they need to navigate this evolving landscape.

#### **Practical session: Emulated or simulated**

3.40 – 4.35pm – ROOM 1-2 & 3

**Moderator** David Perol (Unicancer)

**Speakers** Alison Antoine (Centre Léon Bérard), Suzette Delaloge (Gustave Roussy Institute), Alexandre Templier (Quinten)

#### **Practical session: AI to increase and optimize**

3.40 – 4.35pm – AMPHI B

**Moderator** Raphaël Porcher (Université Paris Cité)

**Speakers** Felix Balazard (Owkin), Stéphanie Allasonnière (PR[AI]RIE), Thomas Walter, (Institut Curie), Gautier Schreiner (HDH)

## Coffee break





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## **AI, in silico and external arm :** time to make them real

### Time to move on

4.50 – 5.40pm – AMPHI A

**Moderator** Yann Maël Ledouarin (DGOS, Ministry of Health)

**Speakers** Andrew Thomson (EMA), Tala Fakhouri (FDA), Sarah Zohar (INRIA-INSERM), Corinne Blachier-Poisson (Amgen)

Which roadmap to bring this future closer and real ? Discussion on the path to follow to create trust..

### Keynote – Witness of the Day

5.40 – 6.00pm – AMPHI A

Lionel Collet – President of French National Authority for Health (Haute Autorité de santé)

### Wrap up and conclusion of the day

6.00 – 6.15pm – AMPHI A

Lise Alter, General Manager Of The French Health Innovation Agency

## End of the day