From EIC-funded research towards real-world practice

- a case of the EIC Pathfinder EVO-NANO project interacting with EMA -

EVO NANO

"Evolvable platform for programmable nanoparticle-based cancer therapies"

EIC-funded project, started in 2018.

Multi-scale simulator to predict and optimize the effect of nano-delivery systems on a tumor. Use a combination of AI and biological simulations to predict treatment effects but also to optimize those treatments. The idea was to eventually offer personalized treatment suggestions to patients.

Motivation for contacting EMA

Is this idea really applicable in a clinical setting?

What are the regulatory requirements?

- Are we developing software as a medical device?
- Does changes in functioning, as a result of AI-induced adaptations, change regulatory status?
- What changes in software will require notifications to EMA?
- if this is used for precision medicine, what level of accuracy should it have?
- What are the regulatory requirements to use this software in organizing clinical trials
- If it is used only in early drug discovery does it goes under any regulatory scrutiny

...and so on.

Feedback we received

ITF Briefing Meeting

"informal exchange of information and guidance in the development process"

- **3 step procedure**: ITF Briefing Meeting request form => draft Briefing Document (BD) => final BD
- **BD**: define topics for discussion and for each topic provide a detailed explanation of our position
- From the initial request to the final approval: approximately **3-4 months** (mostly on our side to precisely outline the BD)
- Representatives: 4 EVO-NANO vs. 22 EMA (7 EMA participants + 15 EMA experts)
- Discussion topics
  - the current stage of the technology;
  - regulatory classification of our technology;
  - regulatory implications of the use of AI;
  - our ideas for future development and EMA's stance on that.
- We got precise answers where possible and guidance when our questions were vague

Post-meeting changes & Next steps

Developing a market ready product is the only way to move novel technology out of the lab and really help society and knowing regulatory requirements is essential precondition.

Intended use
&
indication of use
has been radically redefined

Significantly changed technology development path

EIC Transition business plan created around those changes

We are starting a new Horizon Europe project (BioMeld: A Modular Framework for Designing and Producing Biohybrid Machines), and learning from the previous experience:

- We integrated consultations with EMA into the workplan, and put it early in the project
- We integrated mechanisms to continuously keep an eye on the requirements for market penetration