



# The EU's Political Drive for Clinical Trials

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# Not suddenly waking up to the need for supporting clinical research and clinical trials

Commission long standing engagement

- Horizon Europe funding
- EU4Health programme
- ACT EU (2022)
- Pharmaceutical Reform (2023)
- Commission Communication *“Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU”* (COM (2024) 137)

# Transition to new European Commission (2024-2029)

- Political guidelines from President Von der Leyen :
  - Biotech Act
  - Life Science Strategy
- Hearings of candidate Commissioners in the European Parliament early November 2024
- Confirmation of the Commissioners later in November, which is the basis for the new European Commission to start
- All initiatives need to be politically validated before detailed work can start at the level of the services
- Mission letters for Commissioner designate

# Several studies highlight the importance of supporting clinical research and clinical trials

- Report commissioned by the Council – ‘Letta report’ on future single market
  - Divergent legislation and ethics committee assessment between countries – monitor the situation and promote alignment and collaboration
  - Encourage training of highly qualified pharmaceutical professionals and promote researcher mobility and mutual recognition of professional qualifications
  - Support creation of transnational [clinical] research networks between large research hospitals
  - Launch public awareness campaigns on the importance of clinical research
- Report commissioned by the European Commission – ‘Draghi report’ on competitiveness
  - Streamline set-up and management of multi-country trials in the EU to advance the EU as an attractive place for conducting clinical R&D
  - Increase and focus public R&D investment in the EU (e.g. ATMP hubs)

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# Thank you



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