

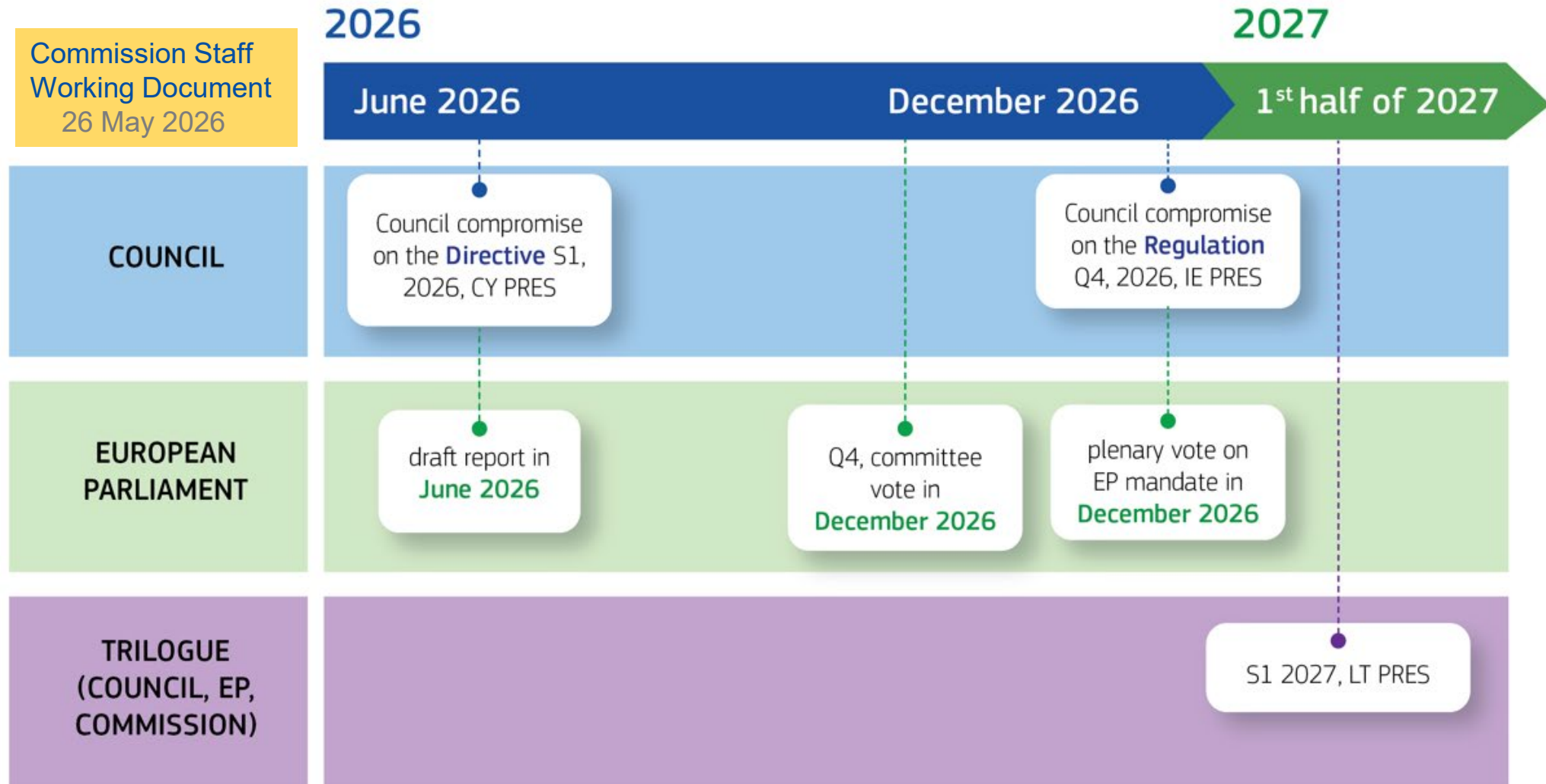


Update on Clinical trials/Biotech Act

June 2026

*European Commission, DG SANTE
Director: Medical Products and Innovation*

Update on BTA – Possible timing on the legislative process



Where do we stand now?

Baseline

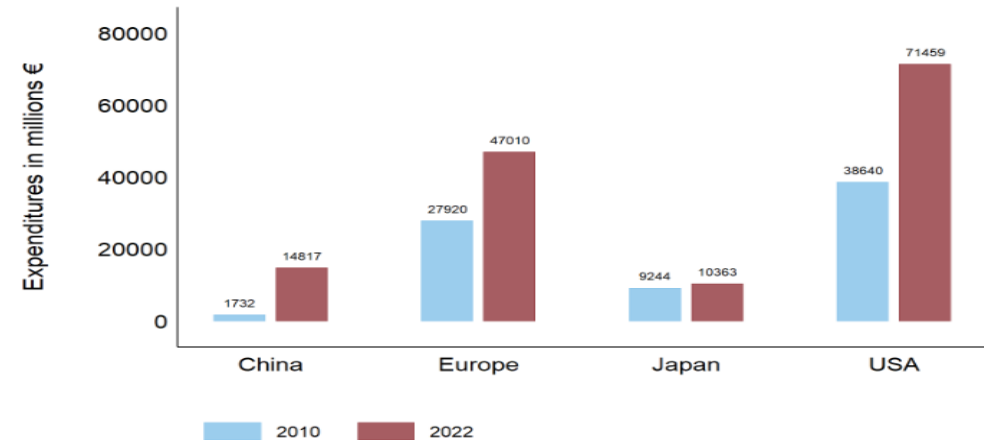
Clinical Trial Activity

- Globally the number of clinical trials has been substantially increasing over the last decade.
- Shift in geographical distribution of clinical trials.
 - EEA's share of global clinical trials declined from 18% in 2013 to 9% in 2023
 - China's share increased from less than 10% to nearly 30%

Key Take-aways

- **PAST TREND:** The EU did not capture a proportional share of the growth in clinical trials.
 - Leading to a **widening competitiveness gap** relative to other regions with potential implications for **economic performance and patients in the EU.**
- **FUTURE:** Risk of this gap widening further unless the regulatory framework is strengthened to increase the attractiveness of conducting clinical trials.

Pharmaceutical R&D expenditures*



Key Changes

Accelerated authorisation timelines	<ul style="list-style-type: none">• Faster assessment timelines for initial applications and substantial modifications• Removal of extra 50-day assessment phase for ATMP trials
More predictable and efficient authorisation procedures	<ul style="list-style-type: none">• Greater reliance on the reporting Member State• More predictable timelines (7-day system)• Introduction of a product core dossier containing documents common elements to all trials with the same medicinal product• Increased inclusivity through increased participation rights for vulnerable population
Context-specific authorisation procedures	<ul style="list-style-type: none">• Single assessment procedure for combined studies• Fast-track authorisation procedure in the context of Public Health Emergencies• Strengthened risk-proportionate approach
Innovation and Harmonised Data Governance	<ul style="list-style-type: none">• Integration of AI and digital tools• Decentralised trial elements, including direct shipment to patients and e-informed consent• Regulatory sandboxes• Single legal basis for processing of personal data
Governance and Enforcement	<ul style="list-style-type: none">• Increased trust and reliance between Member States• Supervision by Member States

Assessment of the impact of the proposed measures

Economic Impacts

Competitiveness: Boost competitiveness based on survey results from industry, academics and Member States

Commercial Trials

Economic gains: EUR 3.6bn to EUR 10.7bn per year

- **GVA*:** EUR 2.2bn to 6.5 boost GVA
- **R&D spill-over:** EUR 0.4bn to EUR 1.1bn
- **Work productivity:** EUR 1bn to EUR 3.1bn

Employment: 16,500 to 49,500 additional jobs per year

Simplified cost-benefit analyses (based on different methodologies and assumptions)

(1) Annual cost-savings of EUR 1.24bn for a subset of policy measures included the proposal

(2) Annual direct cost savings for sponsors of EUR 1.5bn to 3.1bn and indirect savings of the same amounts for sponsors (considering the total set of measures included in the proposal)

~ 10% to 30%
more clinical
trials in the EU



Public Health Impacts

Increased inclusivity

- through strengthened rights for vulnerable population
- Introduction of decentralised elements

Additional participants enrolled per year

- **in commercial trials:** 7,847 to 23,540
- **in non-commercial trials:** 10,381 to 31,145

➤ **Increased access to new treatments by 5 to 10 years**

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*GVA – Gross Value Added

EU4Health Programme – update

AWP 2025

Grants below approved and expected to be signed in November 2026

- **SUPPORT-NCS** – Direct grants to MS authorities to support non-commercial sponsors active in Clinical Trials
- **Budget:** EUR 1 800 000
- **Objective:** *facilitating preparation of high-quality clinical trial applications and increase multi-national clinical trials in the EU/EEA*

- **FACT-EU (ACTOR-tbc)** – Direct grants to MS authorities to support implementation of the CTR and to improve the clinical trials landscape with MS and EEA countries, including through pilots and training
- **Budget:** EUR 4 700 000 *[will take over FAST EU pre-pilot of HMA]*
- **Objective:** *Faster, simpler clinical trial authorisation process, increase multi-national clinical trials in the EU/EEA and enhance compliance with GCP requirements*

Draft AWP 2026

Discussions with MSs are ongoing

Thank you!