Commission proposal for an European Biotech Act

Edit Szepessy

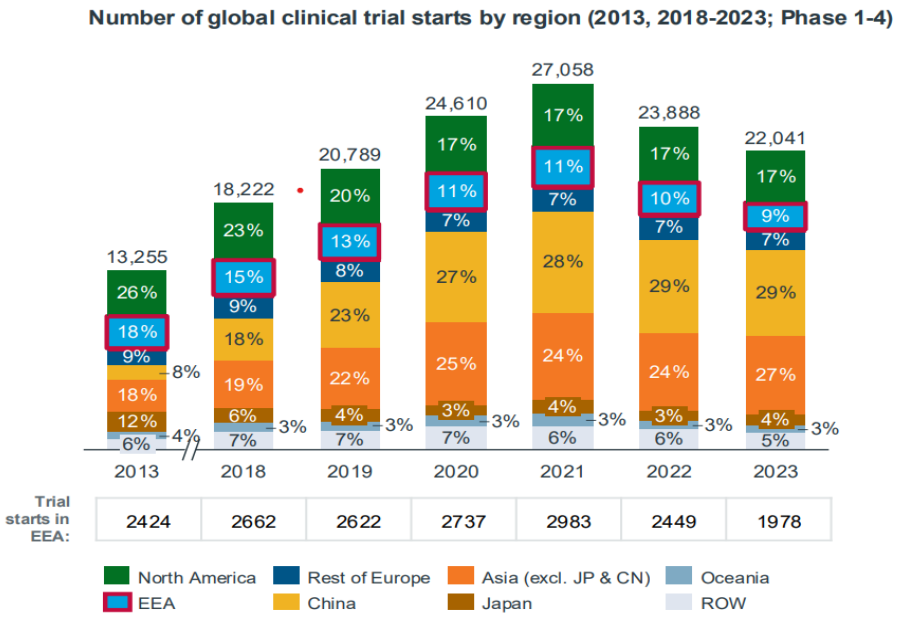
Policy Officer, DG SANTE, European Commission

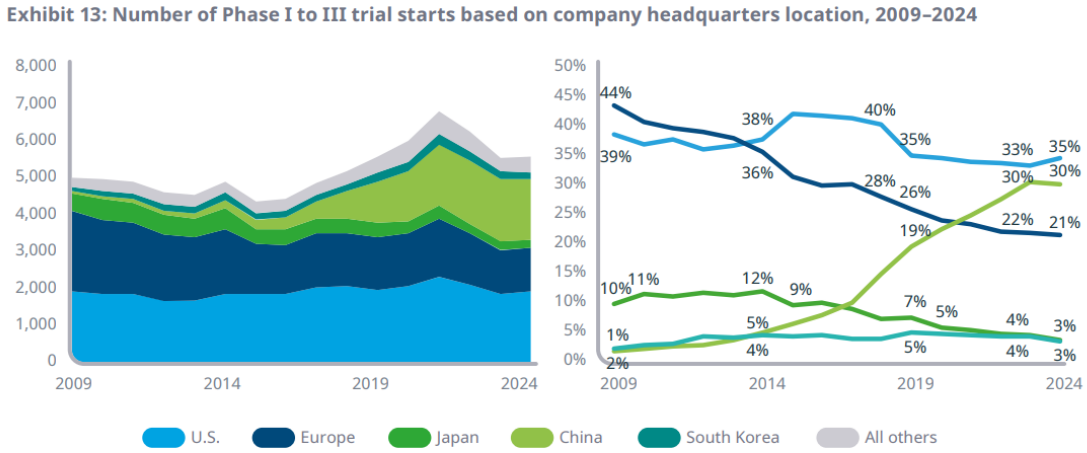
CTIS Information Day Webinar, 17 June 2026

Europe is losing global share

Europe remains a global leader in clinical trials, but its share is declining as other regions are increasing regulatory agility

Global Trend





Source: Citeline Trialtrove, Jan 2025; IQVIA Institute, Jan 2025.

Sources: EFPIA [assessing-the-clinical-trial-ecosystem-in-europe.pdf](), IQVIA global trends in RnD 2025

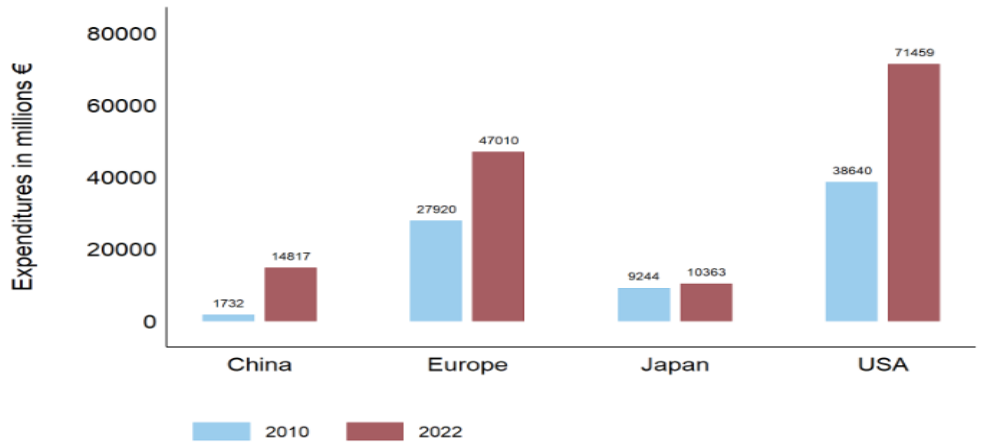
European Commission

Europe is losing global share

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%

Pharmaceutical R&D expenditures*



Key Take-aways

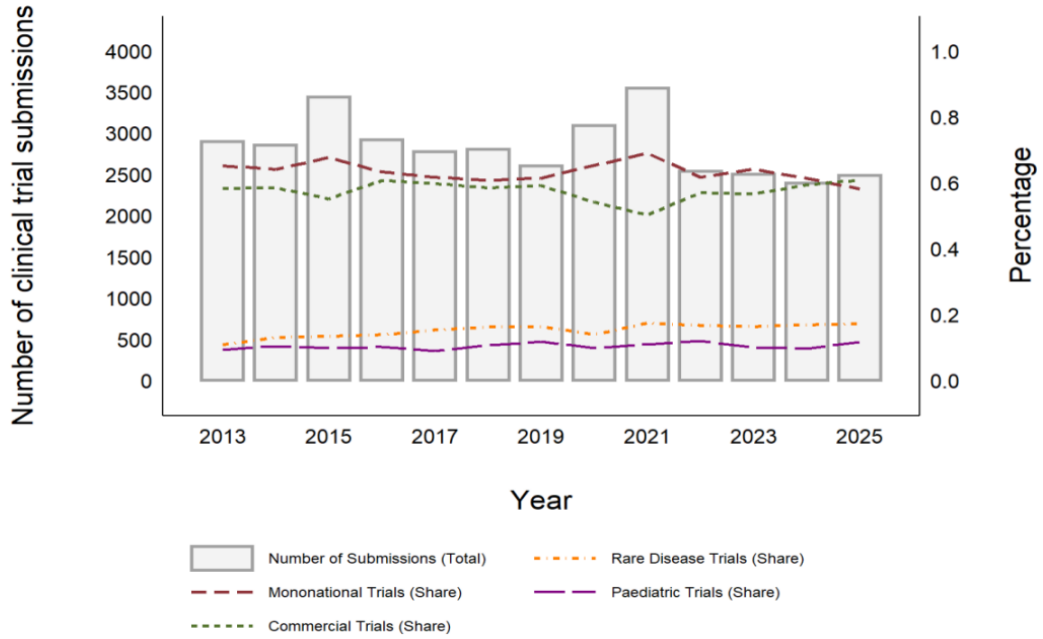
- **PAST TREND:** The EU did not capture a proportional share of the growth in clinical trials.
  - ➢ Leading to a **widening competitiveness gap** relative to other regions with potential implications for **economic performance and patients in the EU.**
- **FUTURE:** Risk of this gap widening further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

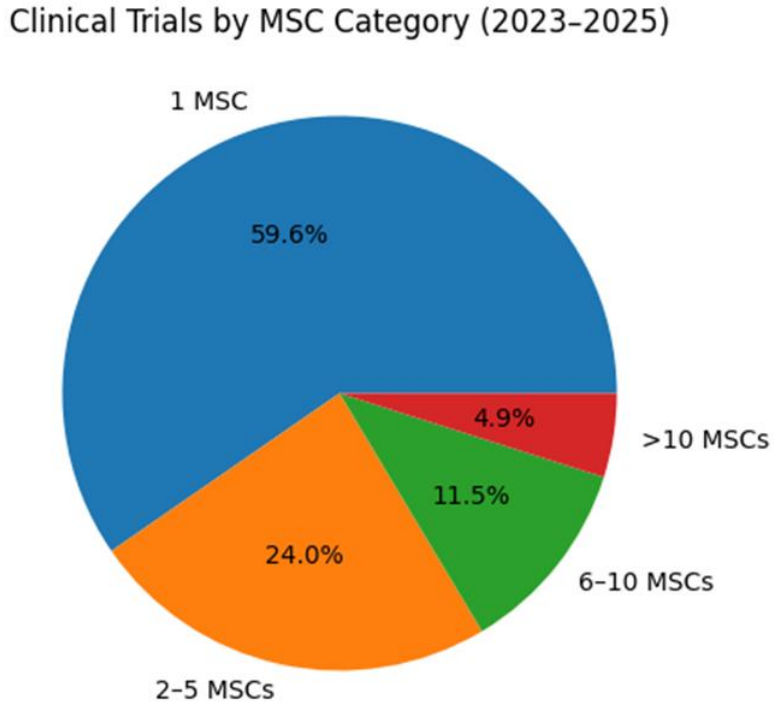
- approximately 60% of the expenditures can be on average allocated to clinical trials (Source: EFPIA report 2024)

CTR improved coordination but trial volumes have not increased and fragmentation persists

Improved coordination and transparency under the CTR has not translated into higher application volumes.

Figure 2. Clinical trial activity in the EU[128]





EU clinical trials during the 3-year CTR transition period
data collection: 31 january 2022- 30 January 2025

European Commission

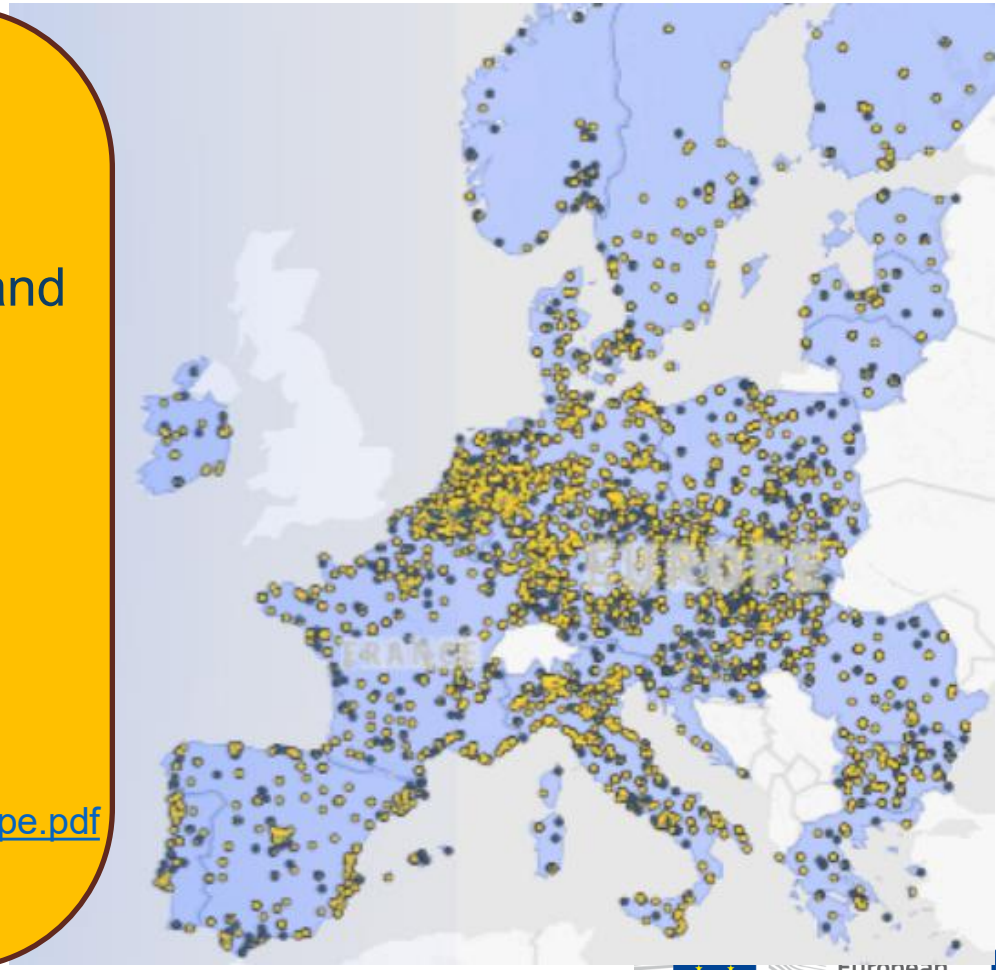
Why clinical trials matter for Europe

Clinical trials are public health and economic performance

- **500 000+ patient per year access innovative or improved treatments, including** for rare diseases and cancers
- **Stronger scientific excellence and skills**
- **€35.7 billion to the EU gross value added (GVA)**
- **165,000 jobs (for commercial trials)**

EFPIA report (2026): the-economic-impact-of-industry-clinical-trials-across-europe.pdf

Commission SWD for the Biotech act: 48009973-efbb-4101-ae8f-e81a34764e39_en



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Even modest increases could generate substantial benefits

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

Economic Impacts

Commercial Trials

- **EUR 3.7 to EUR 10.7bn per year**
- **16,500 to 49,500 additional jobs**

Public Health Impacts

Additional participants enrolled per year:

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

=> Earlier access to innovation by 5 to 10 years

European Commission

Commission SWD for the Biotech act: 48009973-efbb-4101-ae8f-e81a34764e39_en

Regulatory simplification in health biotechnology

Targeted regulatory reform of clinical trials	
Fast	• 106->75 days (initial), 96->47 days (substantial modification) • Parallel substantial modifications
Simpler	• RMS-led assessment, including for ethical review • Product core dossier • Risk proportionate approach • Communication platform
More harmonised	• Combined studies • EU common templates • PHE trials
Digital	• AI and decentralized trials • Regulatory sandboxes • Single legal basis for processing of personal data

Faster authorization without lowering standards

		Validation				Assessment Phase						Decision
		Doc. cons	Submit RFI	RFI response	Submit val. conc	Circulate DAR	Doc consider.	Submit RFI	RFI response	Coord. review	Submit conclusion	Notification
Without RFI	CTR	7	-	-	10	36	48	-	-	-	55	60
	BTA	7	-	-	7	28	35	-	-	-	42	47
With RFI	CTR	7	10	20	25	51	63 *	70	82	94 *	101	106
	BTA	7	7	14	21	28	35	42	56	63	70	75

-23 days **-31 days**

106-> 75 days (see also Stefan Strasser's presentation on FAST EU)

- Stronger RMS (no or shorter coordination and consolidation in validation or assessment, respectively)
- Parallel validation and initial assessment
- Comprehensive assessment with mandatory ethical review
- 7-day basis
- Alignment in part I and II (conditional approvals↓)
- Flexible communication

Source: modified based on EMA slide

Impact to CTIS – Part I SM (art 17-19)

			Validation			Assessment Phase						Decision
		Doc. cons	Submit RFI	RFI response	Submit val. conc	Circulate DAR	Doc consider.	Submit RFI	RFI response	Coord. review	Submit conclusion	Notification
Without RFI	CTR	5	-	-	6	25	37	-	-	-	44	49
	BTA	4	-	-	4	21	24	-	-	-	28	33
With RFI	CTR	5	6	16	21	40	52 *	59	71	83 *	90	95
	BTA	4	4	8	14	21	24	28	35	38	42	47

-19 days

-28 days

-45 days

-48 days

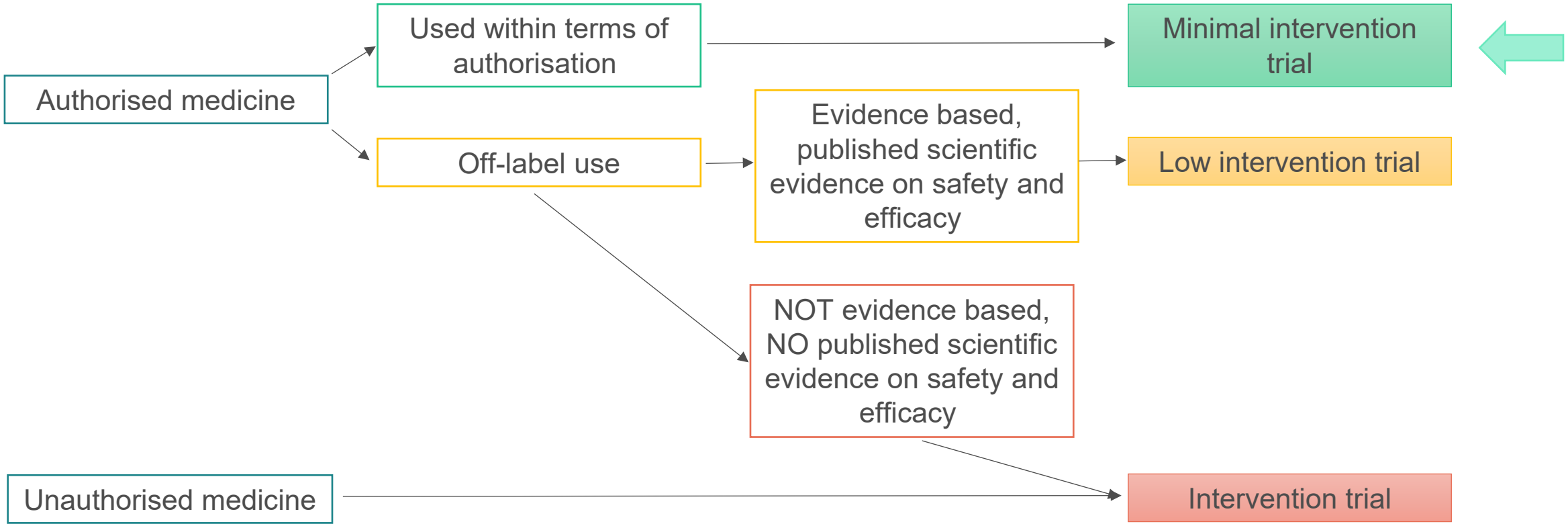
95-> 47 days (48 days):

- Bigger impact of the strong RMS
- Parallel substantial modifications become possible

Comparison: Current CTR vs Biotech Act Proposal

Aspect	Current CTR	Biotech Act Proposal
Validation scope	Part I + Part II	Part I only
Validation responsibility	All Member States	RMS only
Validation process	Coordination & consolidation steps	No coordination or consolidation
Process structure	Sequential	Parallel (overlap with assessment)
Ethical review	Multiple Member States	Mandatory RMS-led review
MSC involvement	Broad and iterative	Limited, justified input only
Ethical scope	Less defined	Clearly defined
Communication	Fragmented	Structured channels
Part I / II timelines	Misaligned	Aligned
Part II templates	Divergent	Mandatory common templates
Conditions		Targeted and flexible
Use of Art 81.9 for document update	limited	More flexible

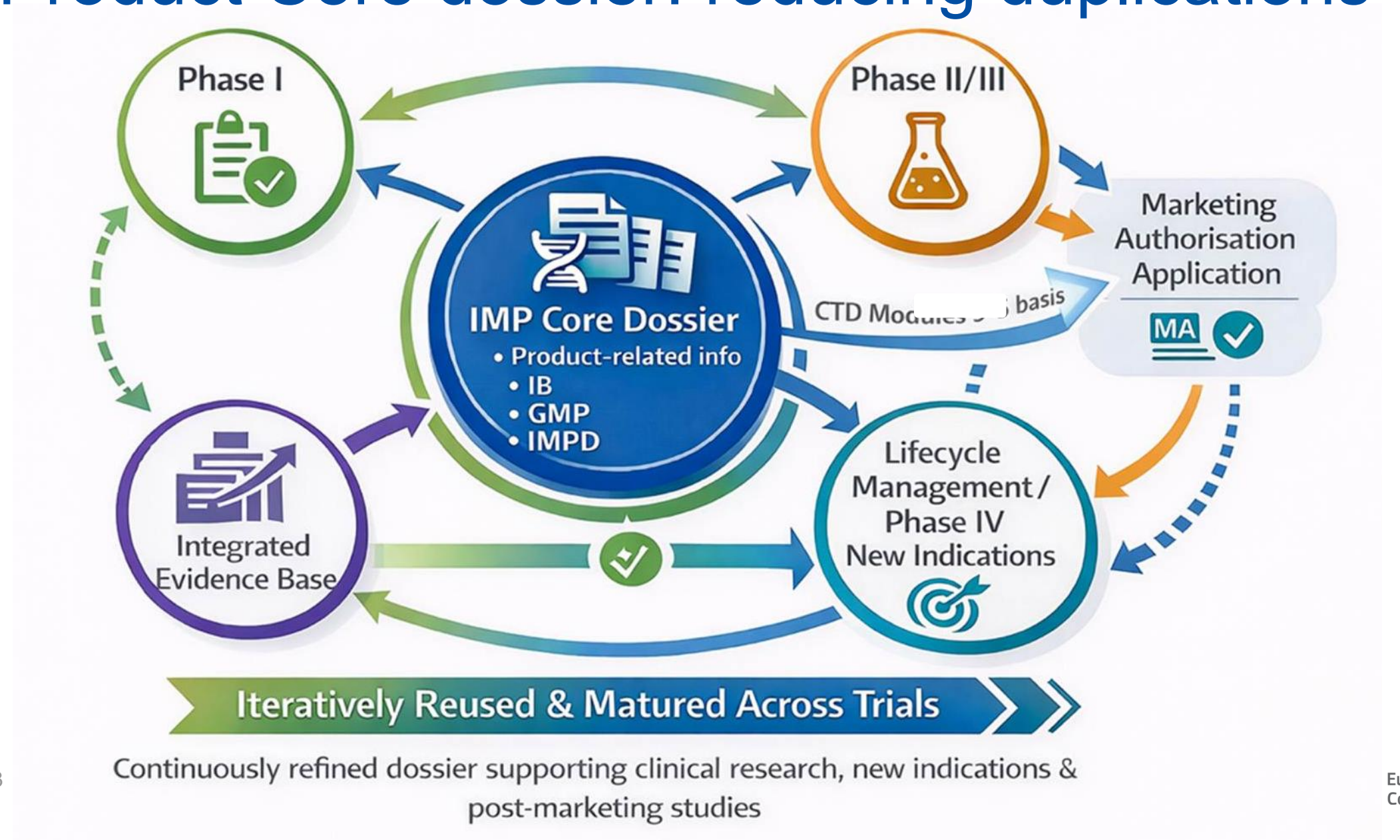
Risk-based approach
Risk categorisation



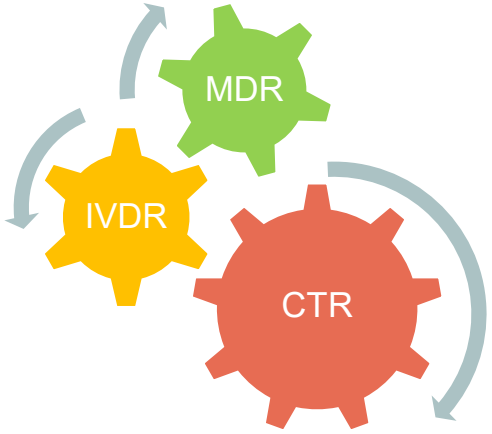
More proportionate approach: LICT, MICT vs interventional trials

	CTR (536/2014)	BTA - Proposal
Authorisation procedure	Same procedure	• minimal-intervention clinical trials: only ethical review • low-intervention, intervention trials: full authorisation
Application dossiers – required documentation	Simplified requirements	• risk adaptions for minimal/low-intervention trials
Trial Conduct	Simplified requirements	targeted and simplified - safety reporting - distribution for IMPs - monitoring

Product Core dossier: reducing duplications



Combined studies: 3 Regulations together



COMBINE PROGRAMME

Authorisation:

Clinical trial of a medicinal product

CT: 3 Member States coordinate using CTIS

? No coordination between the 2 sets of authorisation processes in the Regulations

Performance study of IVD, e.g. for inclusion of patients

MD/IVD: currently 3 national authorisations processes

European Commission

AI across the lifecycle of clinical trials

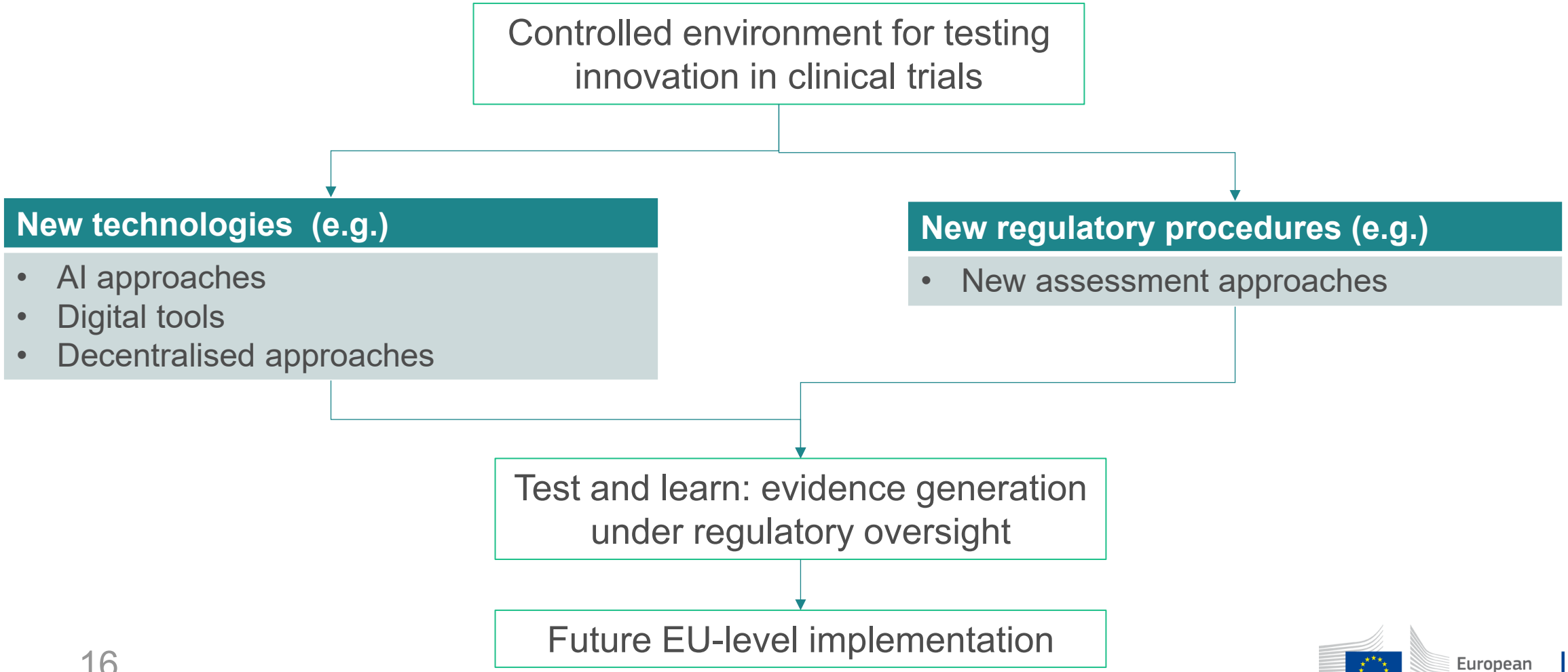
By regulators

- Assessment support
- Information retrieval
- Draft assessment reports

By Developers

- Draft study documentation
- Translations
- Safety monitoring
- Patient selection

Regulatory sandboxes for clinical trials



Key messages

- Europe is modernising the clinical trials regulation
- Faster assessment is achievable
- Regulation becomes more risk proportionate
- Product core dossier is a major opportunity for simplification
- Innovation is enabled through uptake of digital tools, AI and the setting-up of sandboxes

THANK YOU