Council of the European Union
General Secretariat

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LIMITE

SAN	**COMPET**
PHARM	**RECH**
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AGRILEG	**FOOD**
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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (Biotech Act)
Subject:	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Presentation by the Commission

Delegations will find attached the presentation given by the Commission on the CTR revision Commission proposal at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 9-10 July 2026.

CTR revision
Commission proposal



DG SANTE Unit D2, Medical products – innovation, quality and safety

European Commission

#HealthUnion



Agenda Item 3: FAST EU

European Commission

FAST EU: Piloting accelerated assessment

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Objectives:

- Tests the accelerated assessment procedure proposed in the EU Biotech Act
- Pilot coordinated by Heads of Medicines Agencies (HMA) since 30/1/2026
- Generates practical experience to support future implementation and scale-up
- Improves EU competitiveness already now

Key elements:

- 70-day coordinated assessment, + 5 days for national decision step, in total 75 days
- Validation + initial assessment in parallel
- Aligned Part I assessment and Part II assessment
- Fixed timelines based on submission date and 7-day counting

Next steps:

- scale-up, extension to cover also substantial modifications in EU Joint Action HS-25-27 in 2027
- Manuscript with first results

Early experience: overview (July 1 cut-off date)

Demand from sponsors

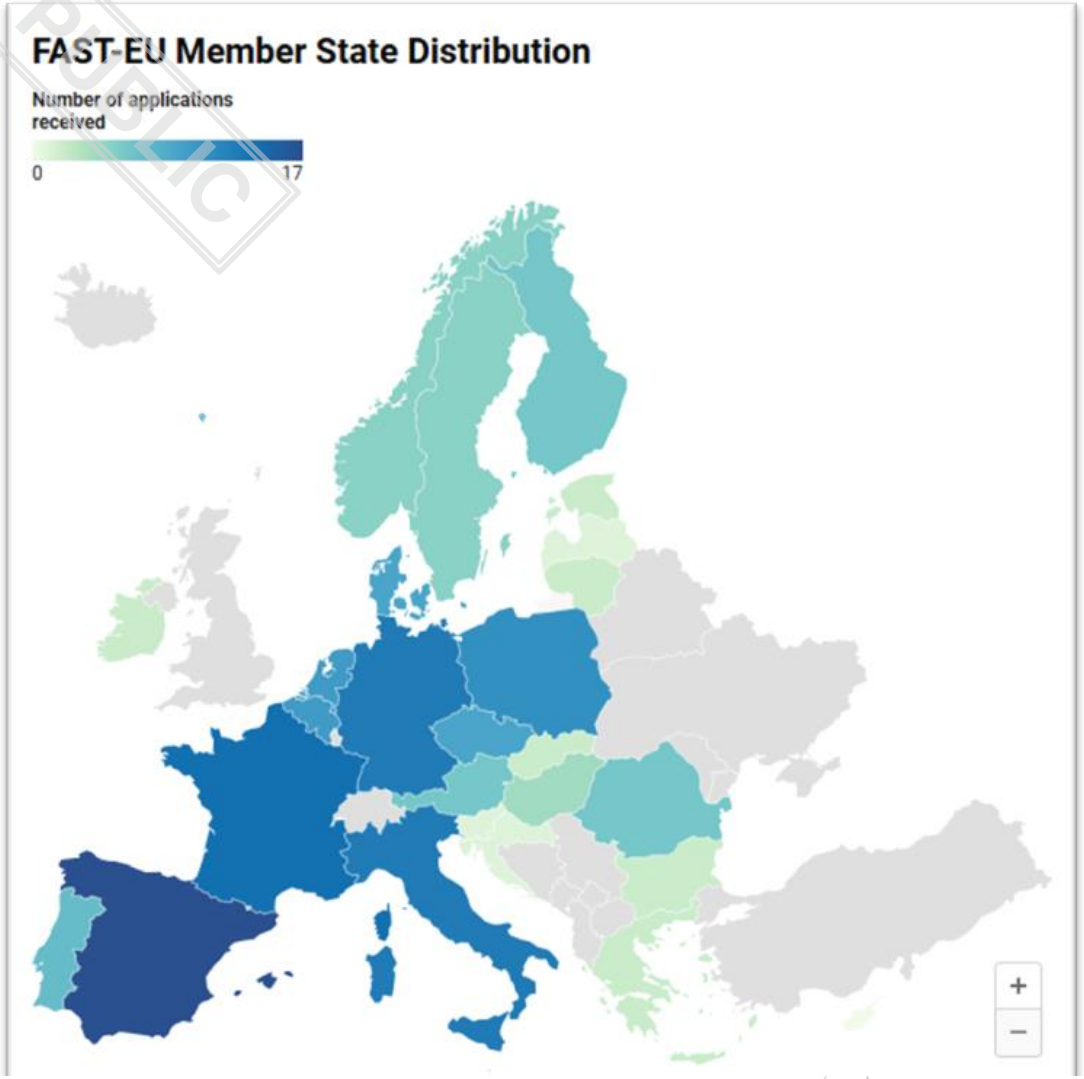
100 expressions of interest
23 procedures accepted so far*
4 applications/months

State of play

19 Reporting Member States (RMS)
21 sponsors
Average 8-9 Member States (MSC) concerned/trial (range: 2-22)

Delivery

all 11 completed in 70 days target
5 in assessment
3 in validation
4 before submission



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Procedures were selected for indication relevance and balanced RMS and MSC coverage.

Early experience: accelerated assessment is possible

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Key findings	
• Accelerated, 70-day assessment is feasible for selected multinational applications • Strong RMS leadership is essential • Accelerated timelines depends on CTIS supports • Rapid communication between RMS (Part I) or MSC (Part II) and sponsors is important	• Validation request for information (RFI) is manageable (not blocking start of initial assessment) • Parallel workflow (validation and initial assessment) can be coordinated • Upfront agreement on RMS is important

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Agenda Item 4: Amendments to the Clinical Trial Regulation

European Commission

Revision of the Clinical Trials Regulation

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Overall objectives:

Reduce regulatory complexity and administrative burden in clinical trials by creating more coordinated, predictable, and efficient processes, while preserving the highest levels of patient safety and data quality.



- supported by corresponding chapter of Staff Working Documents: targeted evaluation and cost-savings analysis

The revision is intended to make the sector **more competitive,** in the internal market and globally,
by supporting innovation for earlier access for patients to innovative and improved treatments.

Key Changes

FASTER, SIMPLER & MORE FLEXIBLE PROCEDURES

- Shortened timelines
- More efficient procedures through greater collaboration across Member States
- Core Dossier allowing for reusable documentation
- Context-specific procedures

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IMPROVED GOVERNANCE & ENFORCEMENT

- Increased trust and reliance between Member States
- Supervision by Member States

INNOVATION & DIGITALISATION

- Integration of AI & digital tools
- Decentralised trial elements
- Regulatory sandboxes

HARMONISATION

- Single legal basis for processing of personal data
- Harmonised EU-wide templates
- Increased inclusivity

European Commission



Agenda Item 4A: General principles and authorisation procedures

European Commission

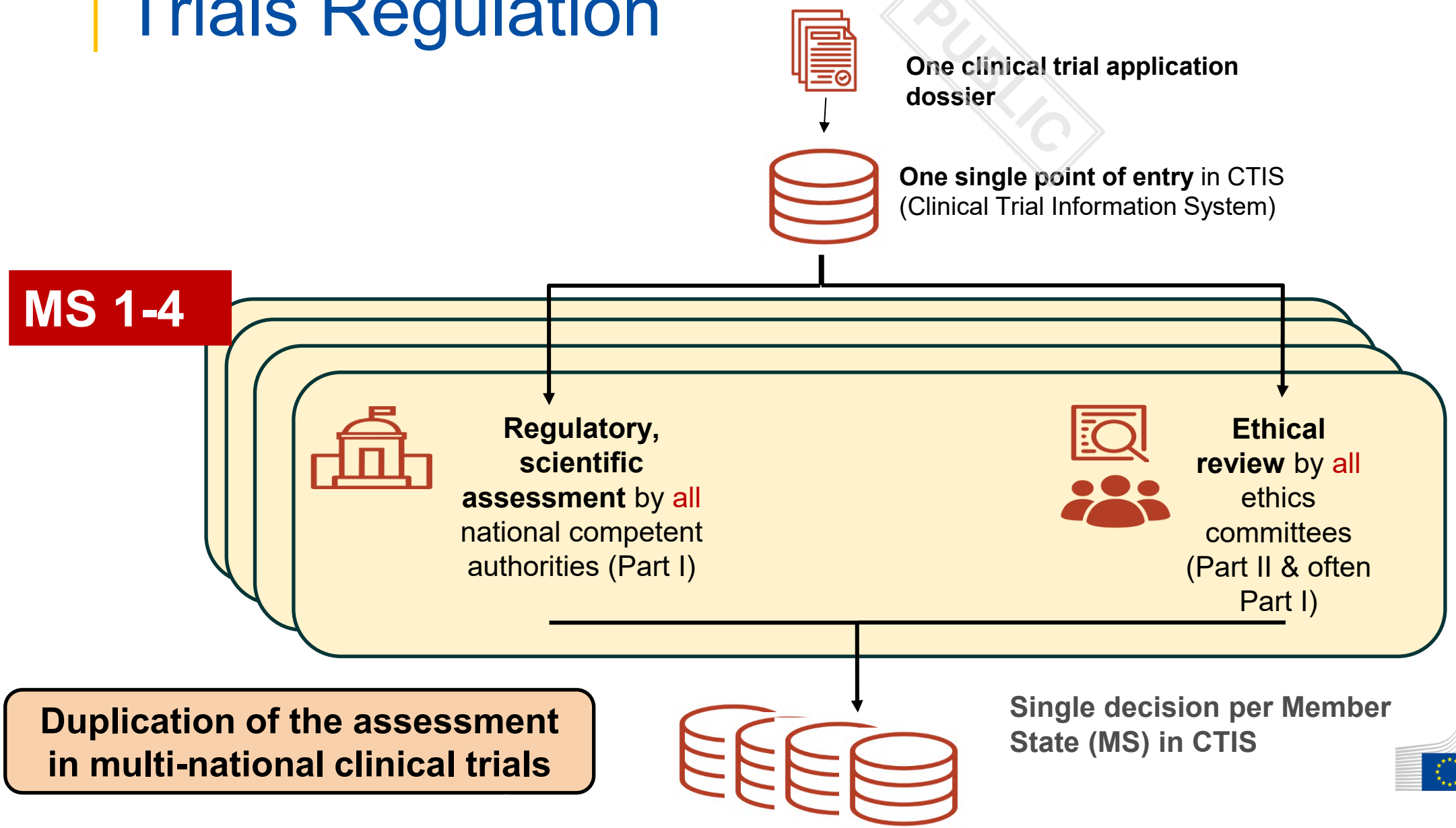
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Articles 3 – 8

A. Standard Procedure

Authorisation procedure under the Clinical Trials Regulation

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Streamlined and faster authorisation procedures in the Biotech Act proposal

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- Standard: 75 → **47 days**
- With RFI in the assessment phase: 106 → **75 days**

Initial authorisation of multinational trials

Substantial modifications

- Standard: 64 → **33 days**
- With RFI in the assessment phase: 96 → **47 days**

- Removal of extra **50**-day assessment phase

ATMP

Improving the initial authorisation procedure

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Key Changes:

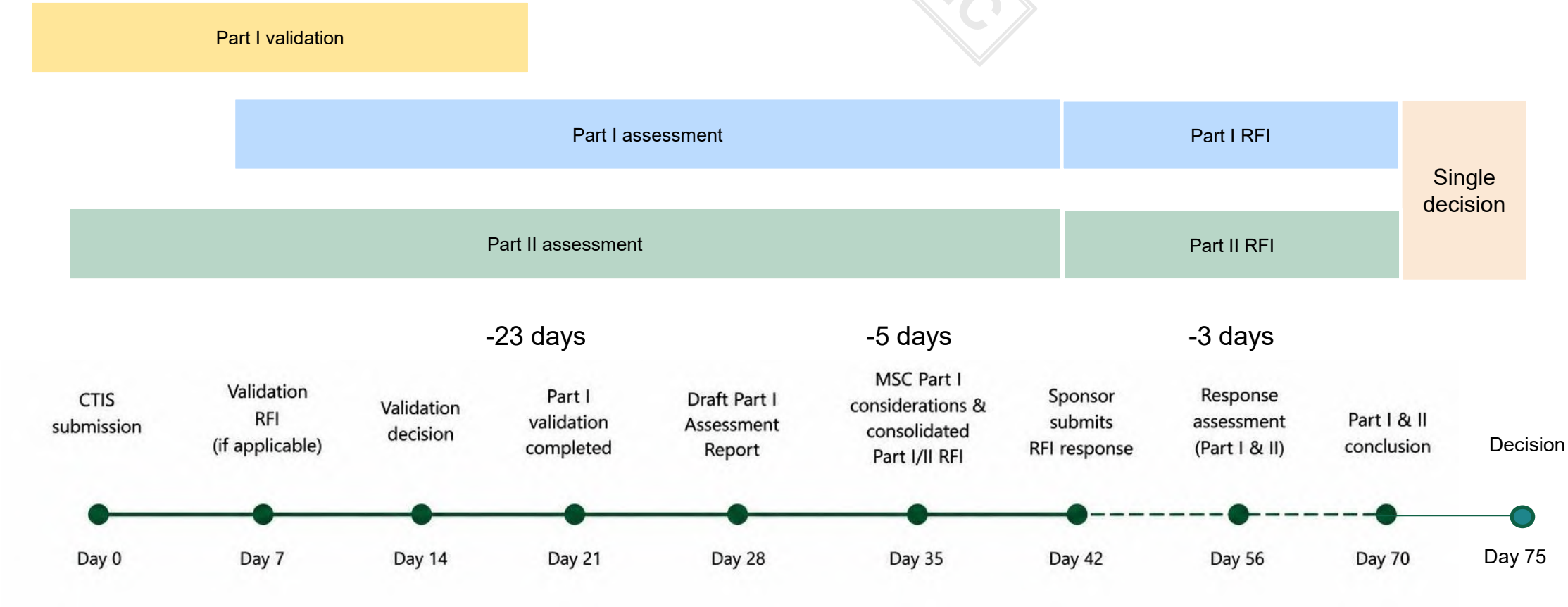
- Greater reliance on the Reporting Member State (RMS):
    - validation is done only by the RMS and only for Part I documents
    - integrated ethical review by RMS reinforcing participants' protection
    - comprehensive scientific, regulatory and ethical review by RMS
    - during the assessment, Member States concerned (MSC) can raise considerations regarding national specificities (e.g. standard of care)
- Procedural restructuring and predictable timelines (7-days system)

Objectives:

- Reduce duplication in Part I
- Streamline validation and ethical review processes
- Limit unnecessary considerations
- Increase efficiency and predictability, reduce administrative burden

Alignment of Part I and II assessments

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Articles 2 – 8

B. Adjustments for minimal/low-intervention trials

Risk-proportionate approach (1/4)

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Challenge:

Complex regulatory requirements and related costs that are not proportionate to trial risk discourage especially non-commercial sponsors from conducting post-marketing authorisation trials in the EU.

Why lower risk trials matter?

Lower risk trials involving authorised medicines generate valuable evidence that improves treatment decisions and patient outcomes.

Current situation:

- Low-intervention trials today account for only 13% of EU-authorised clinical trials.
- Most low-intervention trials are sponsored by non-commercial (academic) organisations.

Risk-proportionate approach (2/4)

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Objective:

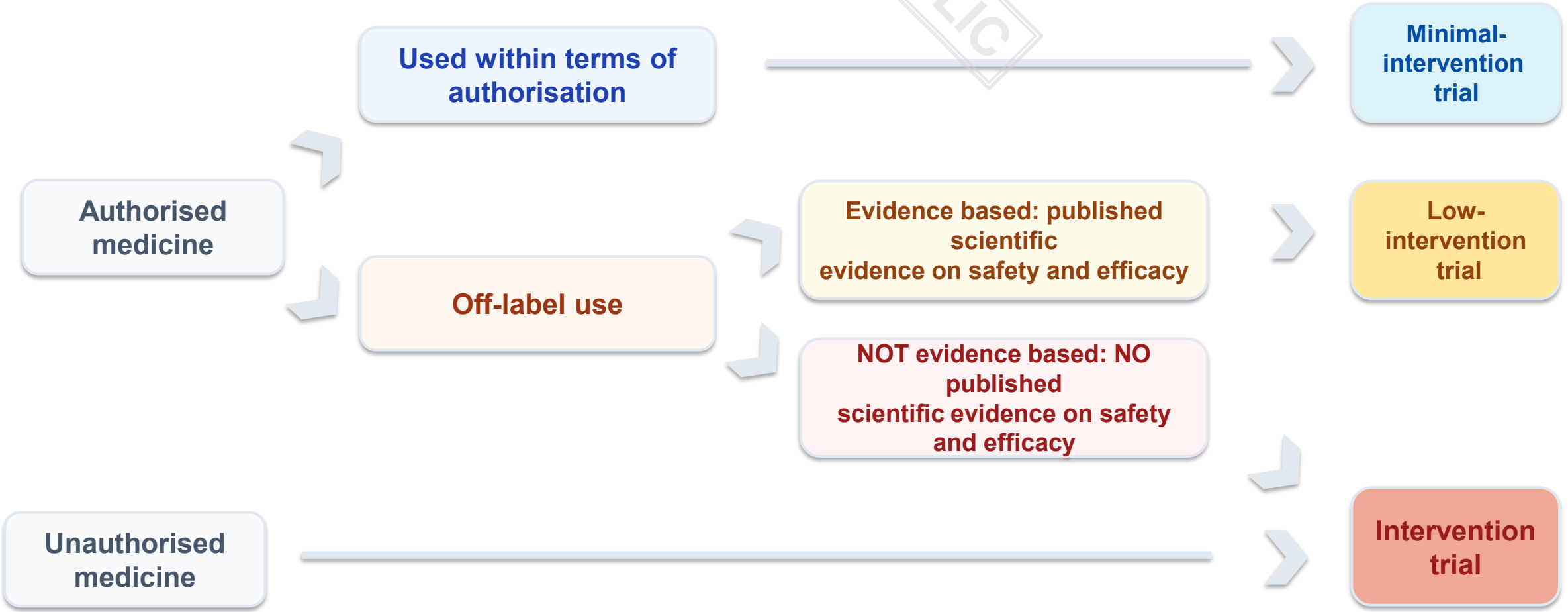
Adopt a more risk-proportionate regulatory approach for the lowest risk clinical trials to reduce unnecessary regulatory burden, promote evidence generation, and ultimately improve patient care.

Key changes:

- Introduction of a general principle:
  - Member States shall apply proportionate regulatory requirements to the risk category of each clinical trial
- Introduction of a new risk category for the lowest-risk trials, with reduced regulatory requirements
- Simplified authorisation procedure for minimal-intervention and low-interventional clinical trials
- Simplified requirements for the conduct of clinical trials (to be discussed in later articles)

Definitions of minimal/low-intervention trials (3/4)

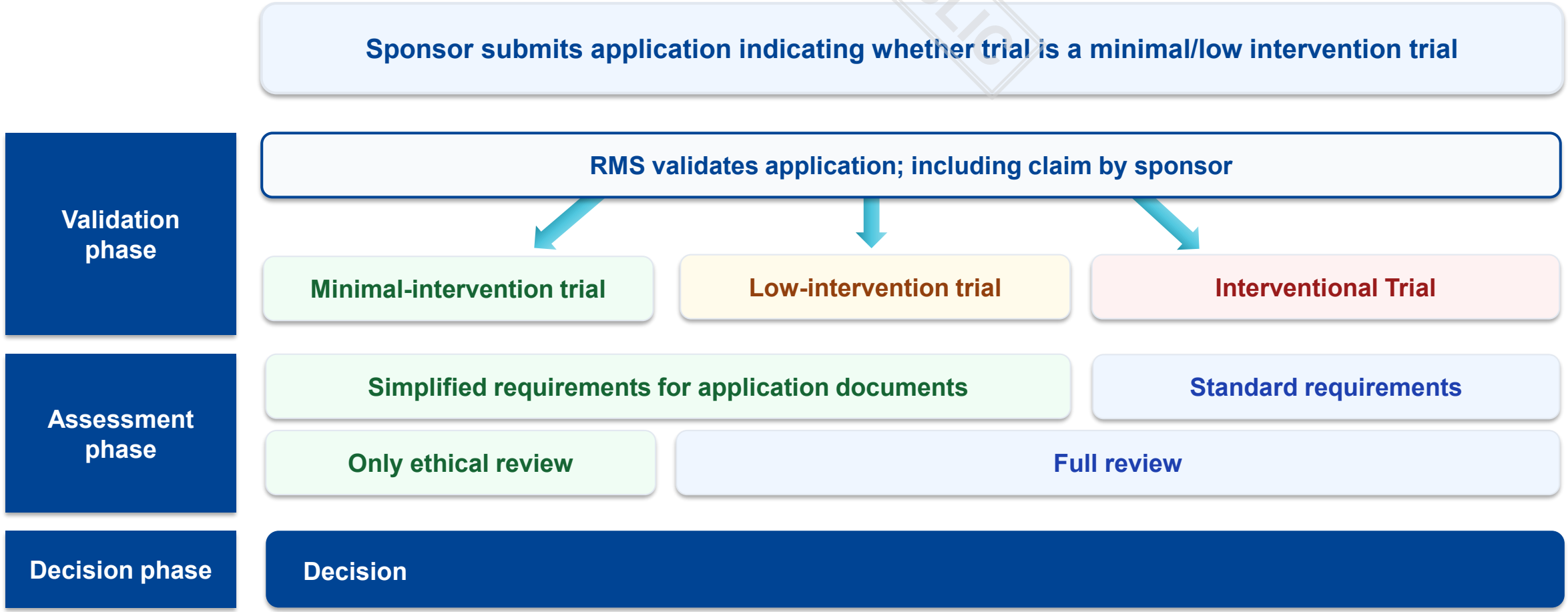
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Differences in requirements in authorisation process across risk categories (4/4)

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Proportionate requirements enable time and cost savings



Article 9

Persons assessing the application

Persons assessing the application

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Key Changes:

- Clarification of independence requirements
- Together with Art. 83, aims to ensure sufficient number of independent, resourced, and empowered assessors.

Objectives:

- Strengthen transparency and confidence in the assessment process
- Sufficient resources, expertise, and authority for assessors to support efficient, high-quality and faster assessments



Article 11
Submission and assessment of applications limited to aspects covered by Part I of the assessment report

Submission and assessment of applications limited to aspects covered by Part I of the assessment report 1/2

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Submission of Part I

- RMS assesses whether the application is valid

If the application is valid, the RMS conducts a first assessment and drafts an assessment report

- MSC can raise considerations and RMS takes them into account

RMS delivers the final assessment report on aspects covered by Part I

- Reporting date with positive conclusion on Part I

No Part II submission within 2 years from positive Part I conclusion

→ Part I application lapses

Willing to submit Part II within 2 years **and** no new scientific information that would affect the validity of Part I assessment? → OK submits Part II
NEW Otherwise submits a SM Part I at the latest, at the same time as the submission of Part II

Submission and assessment of applications limited to aspects covered by Part I of the assessment report (2/2)

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Key Changes:

- Possibility to submit a Part I substantial modification where only Part I has been submitted and thus no decision has been issued
- Coordinated assessment of Part I substantial modifications by all Member States concerned that received the initial application

Objectives:

- Increase flexibility for phased Part I/Part II submissions
- Maintain harmonised Part I assessments across Member States
- Facilitate multinational trial participation, particularly for smaller Member States and academic sponsors

Application dossier: Part I and Part II

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PART I — Conclusion by the Reporting Member State

Study Design & Conduct
Protocol • Investigator's brochure

Investigational Product
Medicinal product dossier(s)

Quality & Compliance
Good manufacturing practice • Labelling

PART II — National Conclusion

Ethics & Participant Protection
Informed consent • Use of biological samples

Site & Operational Readiness
Recruitment arrangements • Site suitability

Legal, Financial & Data Compliance
Insurance • Financial matters • GDPR



Article 14 – Subsequent addition of a Member State concerned

Subsequent addition of a Member State concerned

PUBLIC

Key Changes:

- Align timelines with those applicable under the standard authorisation procedure
- Cannot be submitted where a Part I substantial modification (SM) assessment is already ongoing

Objectives:

- Accelerate timelines without making this route more advantageous for sponsors than submitting the initial application directly to all concerned Member States
- Safeguard the integrity of the assessment process by preventing parallel Article 14 and Part I SM evaluations



Article 14a – Appointment of a new Reporting Member State

Appointment of a new Reporting Member State

PUBLIC

Key Changes:

- Possibility to change the Reporting Member State (RMS), when the trial is not ongoing in this Member State
- Establishes a formal procedure for initiating and managing the transition
- Ensures continuity of ongoing assessments

Objectives:

- Preserve predictability and legal certainty for sponsors and Member States
- Respect fair the work-share principle between Member States
- Ensure that accountability and workload remain aligned with the strengthened RMS role

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Article 14b – Accelerated procedure for public health emergencies

Accelerated procedure for public health emergencies (1/2)

PUBLIC

Key Changes:

- **New**: Introduction of a procedure to accelerate regulatory processes during public health emergencies

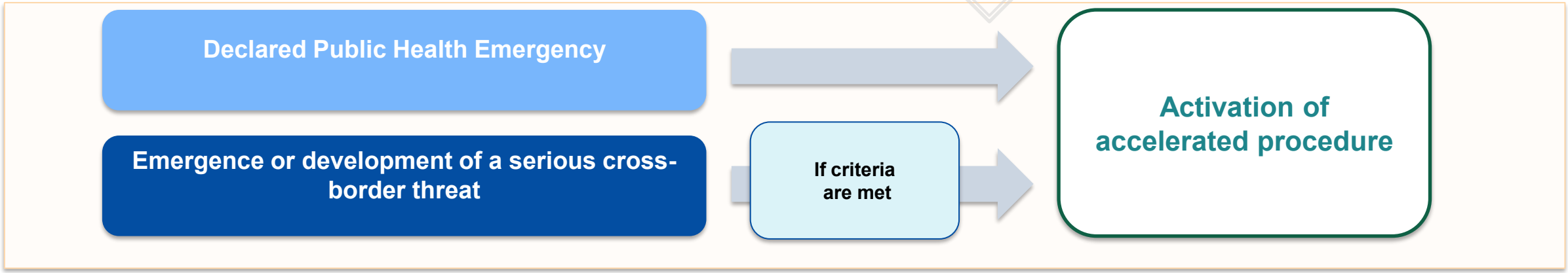
Objectives:

- To ensure the rapid availability of safe and effective medicines relevant to crisis situations during public health emergencies, building on lessons learned from the COVID-19 pandemic
- To accelerate authorisation procedures and simplify regulatory requirements for multinational clinical trials during public health emergencies

Accelerated procedure for public health emergencies (2/2)

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STEP 1: Activation of the procedure at Union level



STEP 2: Fast-track procedure for crisis-related trials

1 **Application submission:** Sponsor must indicate whether medicine is intended to address serious cross-border threat to health

2 **Validation:** RMS verifies claim by sponsor

3 **Assessment:** Shorter assessment timelines, integrated ethical review, and simplified requirements for the clinical trial application dossier. Procedure to be defined via Delegated Acts



COMBINE PILOT

European Commission

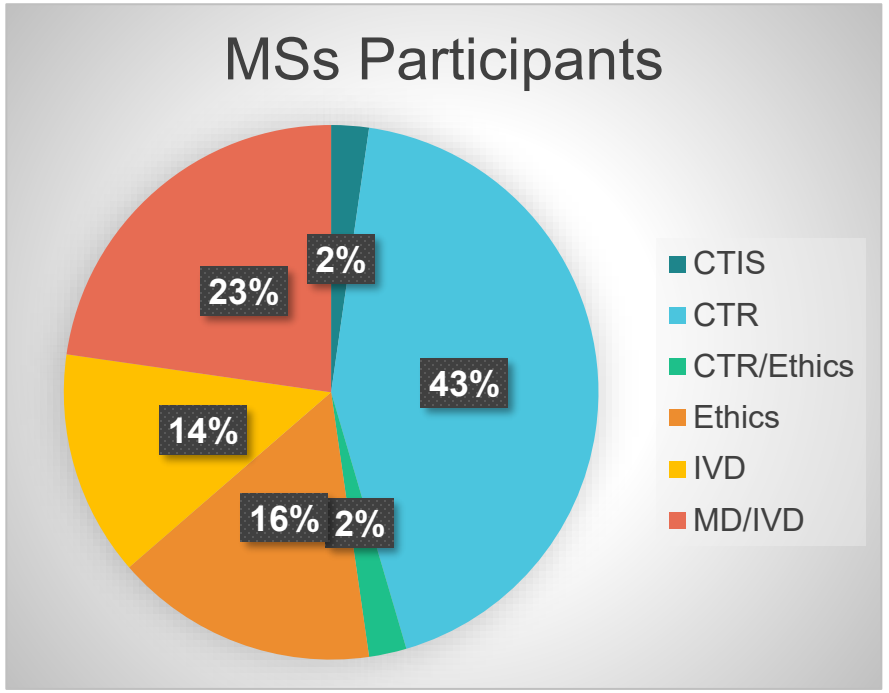
‘All in one coordination of assessment procedures under CTR/IVDR/MDR’ (1/2)

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Purpose: Explore **coordinating** Member State assessments of applications for **combined studies** (CA/EC) across the **CTR and IVDR** or MDR using a CT of a medicinal product combined with PS of a companion diagnostic IVD as case example

Participating MSs:

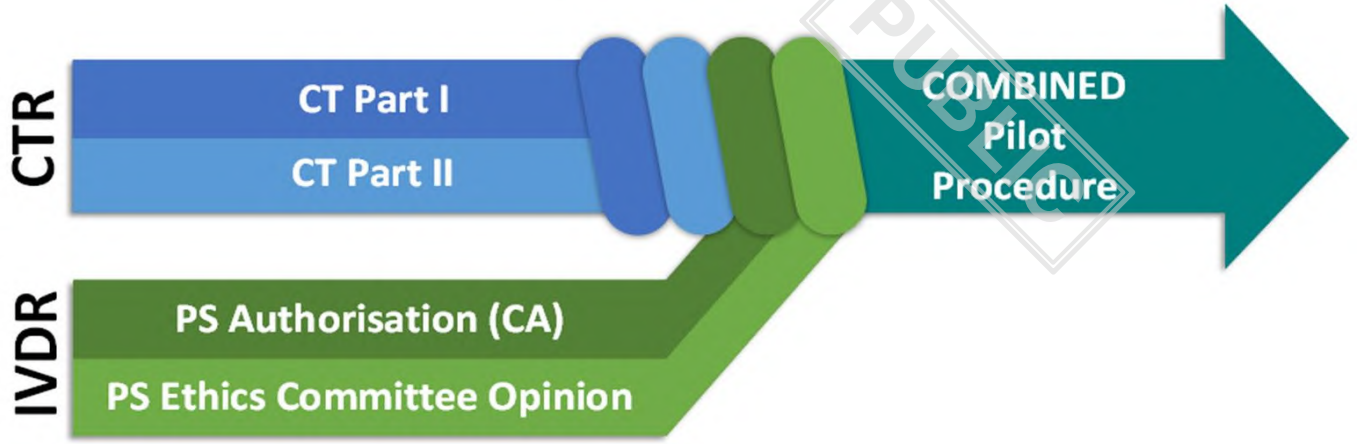
- Ireland (lead)
- Austria (co-lead)
- Belgium
- Cyprus
- Denmark
- Finland
- France
- Germany
- Greece
- Latvia
- Luxembourg
- Netherlands (co-lead)
- Norway
- Portugal
- Romania
- Slovenia
- Spain
- Sweden



18 MS + EMA
50+ participants,

European Commission

COMBINE pilot: all-in-one coordinated assessment (2/2)



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- **Pilot Phase I** launched 13 June 2025
  - Scope: 18 MSs involved with scope limited to combined studies with IVDs and single sponsor
  - 8 applications from 6 sponsors in first pilot phase
  - Timelines of the pilot followed the current CTR timelines : approx. 100 days
  - Live feedback along the process by stakeholders and MSs: Report on lessons learned planned for August 2026

  => 2 assessments concluded as of March 2026 with timelines respected

- **Pilot Phase II** to be launched 26 June 2026: rolling submission of interest (monthly); 18 MSs involved; +MDs, two sponsors , single documentation, ATMPs, substantial modifications



Article 14c – Combined studies

Combined studies: special authorisation procedures (1/3)

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Investigating a medicinal product in a clinical trial (CT) together with an in vitro diagnostic (IVD) in a performance study or a medical device (MD) in a clinical investigation

Examples

Medicine that only works in patients with a specific mutation and **genetic test (IVD)** to detect it

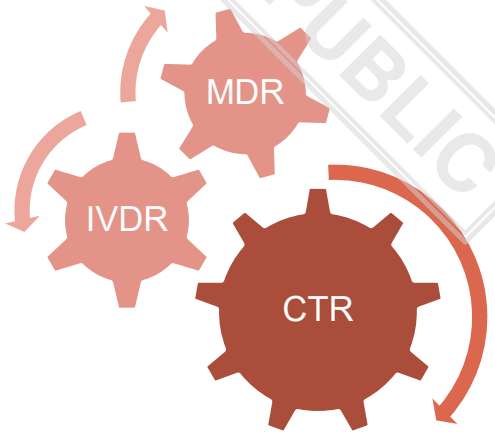


Medicine that needs to be administered by a dedicated **inhaler (MD)**



Combined studies: Applying 3 Regulations together (2/3)

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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, piloting coordinated assessment

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Combined studies (3/3)

PUBLIC

Key Changes:

- Amendments to 3 regulations (CTR, IVDR, MDR)
- New definition of combined study
- Streamlined procedure for the authorisation of combined studies
- One single application submitted to Clinical Trials Information System
- One coordinating sponsor
- One coordinated assessment involving national competent authorities on medicinal products, medical devices and ethics committees
- One national decision

Objectives:

- Address challenges in simultaneous application of CTR/IVDR/MDR to facilitate the development of innovative therapies



Article 25 – Data submitted in the application dossier

Data submitted in the application dossier (1/2)

PUBLIC

Key Changes:

- Adjustments related to risk-based approach
  - Application dossier must include a justification for the categorisation of a minimal or low intervention trial
  - The requirements for Part I of the application dossier and for authorisation of a substantial modification may be adapted for minimal-intervention and low-intervention clinical trials
- Introduction of the mandatory use of EU-templates for Part II documents (where templates are available)
- Clarity on documentary basis for the assessment
- Trial applications can be supported by European Health Data Space (EHDS) data

Data submitted in the application dossier (2/2)

PUBLIC

Objectives:

- To allow regulatory flexibility for minimal- and low-intervention clinical trials
- To foster harmonisation in the documents included in the application dossier
- To enable re-use of EHDS regulatory data and support a more integrated EU clinical research environment
- To reduce fragmentation and administrative burden associated with documentary requests across clinical trials.

PUBLIC

Additional articles related to the risk-based approach

Article 30(3), Article 41(5), Article 48(a), Article 51(1) and Article 57 and Article 76(3)

Reporting of adverse events and serious adverse events by the investigator to the sponsor (Art. 41)

PUBLIC

Key Changes:

- Reporting requirements of adverse events and serious adverse events for minimal-intervention and low-intervention clinical trials **must** be simplified by applying a risk-based approach.

Objective:

- To ensure risk-proportionate reporting requirements



Agenda Item 4B: Substantial Modifications and EU database

European Commission



Article 16 – Submission of application
Article 16a – Parallel substantial modification

Submission of application
Parallel substantial modification

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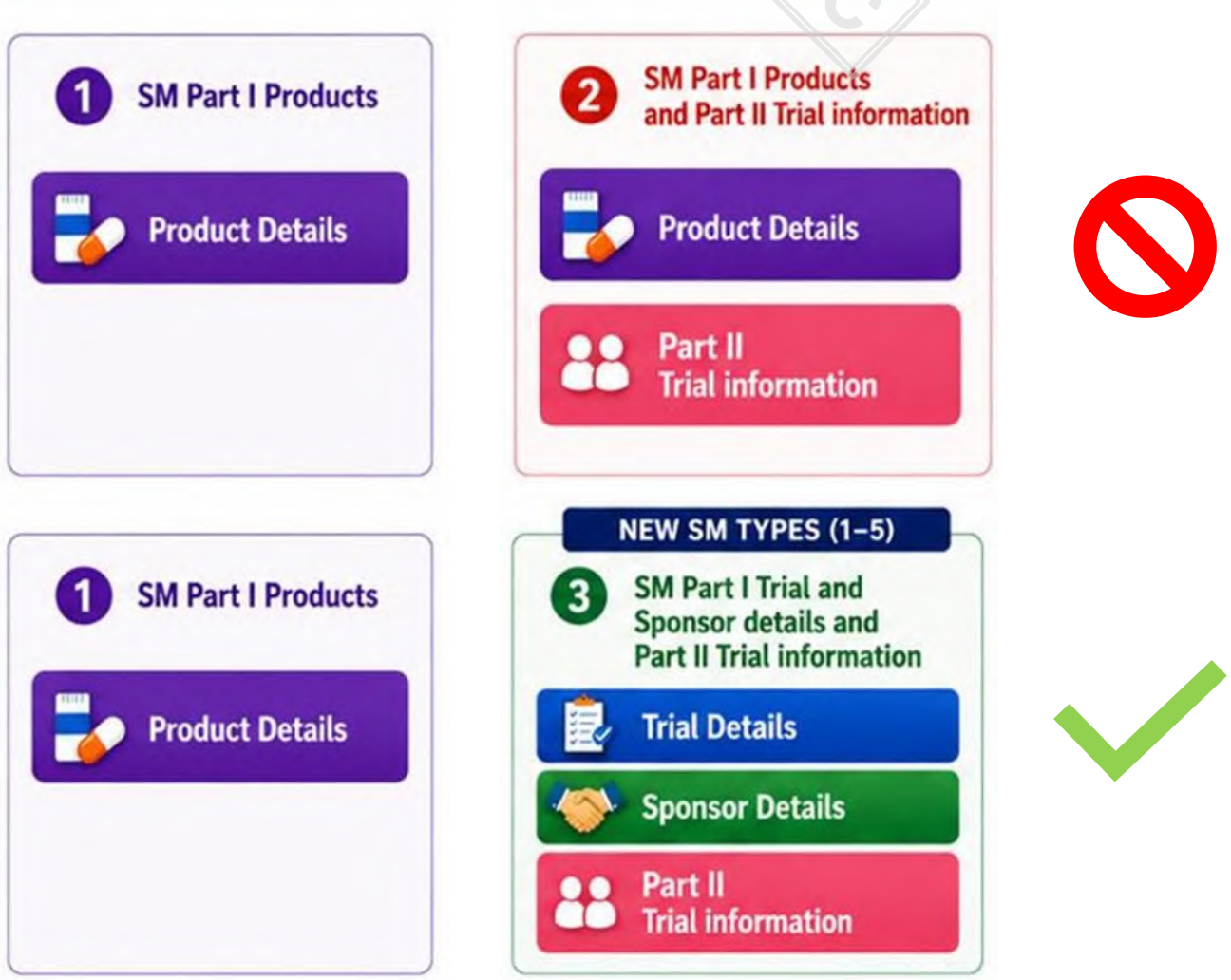
Key Changes:

- Clarification defining the “submission date”
- Introduces parallel substantial modifications (SM)
- Reporting Member State (RMS) or Member State concerned (CMS) must accept parallel SMs if they cover distinct, independent aspects
- Coordination between RMS and CMS for parallel Part I/II SMs

Objectives:

- Uniform interpretation of the submission date as reference point for assessment timelines
- Increase flexibility and efficiency in handling multiple SMs, supporting shorter timelines for their assessments
- Ensure integrity of trial documentation and Member State coordination

Substantial modifications with "distinct and independent" scope for parallel submission -- examples



PUBLIC

Validation of an application for authorisation of a substantial modification of an aspect covered by Part I of the assessment report

PUBLIC

Key Changes:

- Maintain exclusive role of RMS for Part I substantial modification (SM) validation
- Shortens and streamlines timelines
- Translation burden is removed from Part I SM procedure
- Clarifies management of considerations from Part I translations as well as of unacceptable parallel SMs

Objectives:

- Ensure faster and more predictable validation timelines
- Strengthen procedural clarity and parallel SM handling

PUBLIC

Article 18 – Assessment of a substantial modification of an aspect covered by Part I of the assessment report

Assessment of a substantial modification of an aspect covered by Part I of the assessment report

PUBLIC

Key Changes:

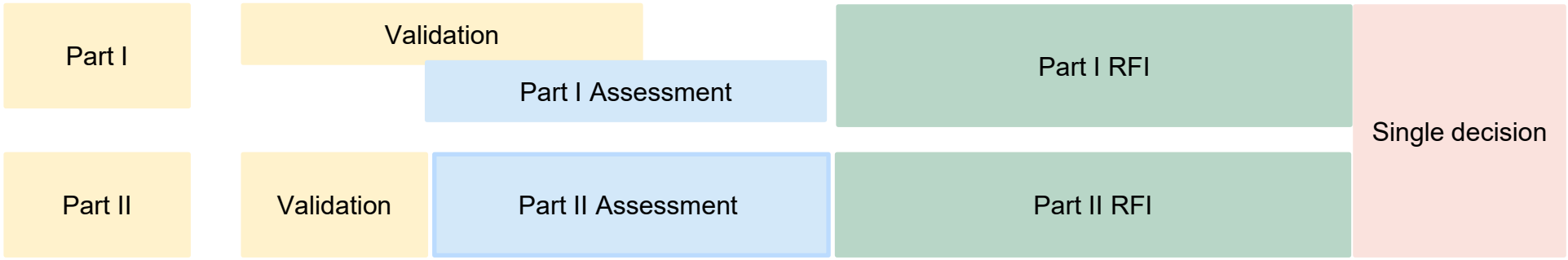
- Parallel validation and initial assessment phases.
- Limited scope for Member States concerned (MSCs) to raise considerations during assessment (both before and after RFI)
- Greater reliance on the RMS

Objectives:

- Stronger reliance on the RMS assessment
- Streamlined procedures
- Simplified applications enabled by parallel substantial modifications
- Reduce timelines and administrative burden while maintaining quality

Alignment between Part I and II substantial modifications

PUBLIC





Decision on the substantial modification of an aspect covered by Part I of the assessment report

PUBLIC

Key Changes:

- Greater flexibility in the use of conditional authorisation
- Narrowed grounds for disagreement by Member States concerned (MSCs) with the RMS conclusion

Objectives:

- Reduce unnecessary refusals and avoid avoidable delays between authorisation and trial start
- Reinforce the weight of the RMS conclusion, consistent with its lead role in the assessment process
- Faster Part I SMs enable quicker protocol and product updates, ensuring earlier implementation of improvements and more rapid patient benefit from harmonised, optimized, safer trial conduct

Article 20 – Validation, assessment and decision regarding a substantial modification of an aspect covered by Part II of the assessment report

PUBLIC

Validation, assessment and decision regarding a substantial modification of an aspect covered by Part II of the assessment report

PUBLIC

Key Changes:

- Shortens and streamlines timelines
- Clarifies management of unacceptable parallel SMs
- Greater flexibility in the use of conditional authorisation

Objectives:

- Faster and simpler Part II SMs aims to enable:
  - quicker site activation, allowing earlier and easier access clinical trial participation closer to their homes
  - patients benefit more quickly from safer, more up-to-date trial conduct



Article 81 (2)-(9) – EU database

EU database

PUBLIC

Key Changes:

- Conditions attached to an authorisation decision to be updated in the Portal
- Addition of a communication platform to the Portal for necessary clarifications between sponsor and assessing country during the assessment

Objectives:

- Simpler and faster fulfilment of conditions
- Reduce unnecessary substantial modification procedures
- Faster trial start
- Efficient and coordinated regulatory follow-up between sponsor and assessing Member State