Council of the European Union
General Secretariat

PUBLIC

Interinstitutional files:
2025/0406 (COD)

Brussels, 22 July 2026

WK 10846/2026 INIT

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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 22-23 July 2026.

Clinical Trial Regulation revision Commission proposal



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

European Commission

#HealthUnion



Agenda Item: Investigational medicinal product (IMP) Core Dossier

European Commission

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Article 27a – Establishment of an IMP Core Dossier

Establishment of an IMP Core Dossier

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Key Changes:

- Formal IMP Core Dossier concept
- Single assessment by the depositary Member State and reliance by Member States Concerned (MSC)
- The IMP Core Dossier shall be re-used for corresponding clinical trials
- Establishment following a positive assessment of completeness and suitability
- EU portal-based (CTIS) lifecycle management

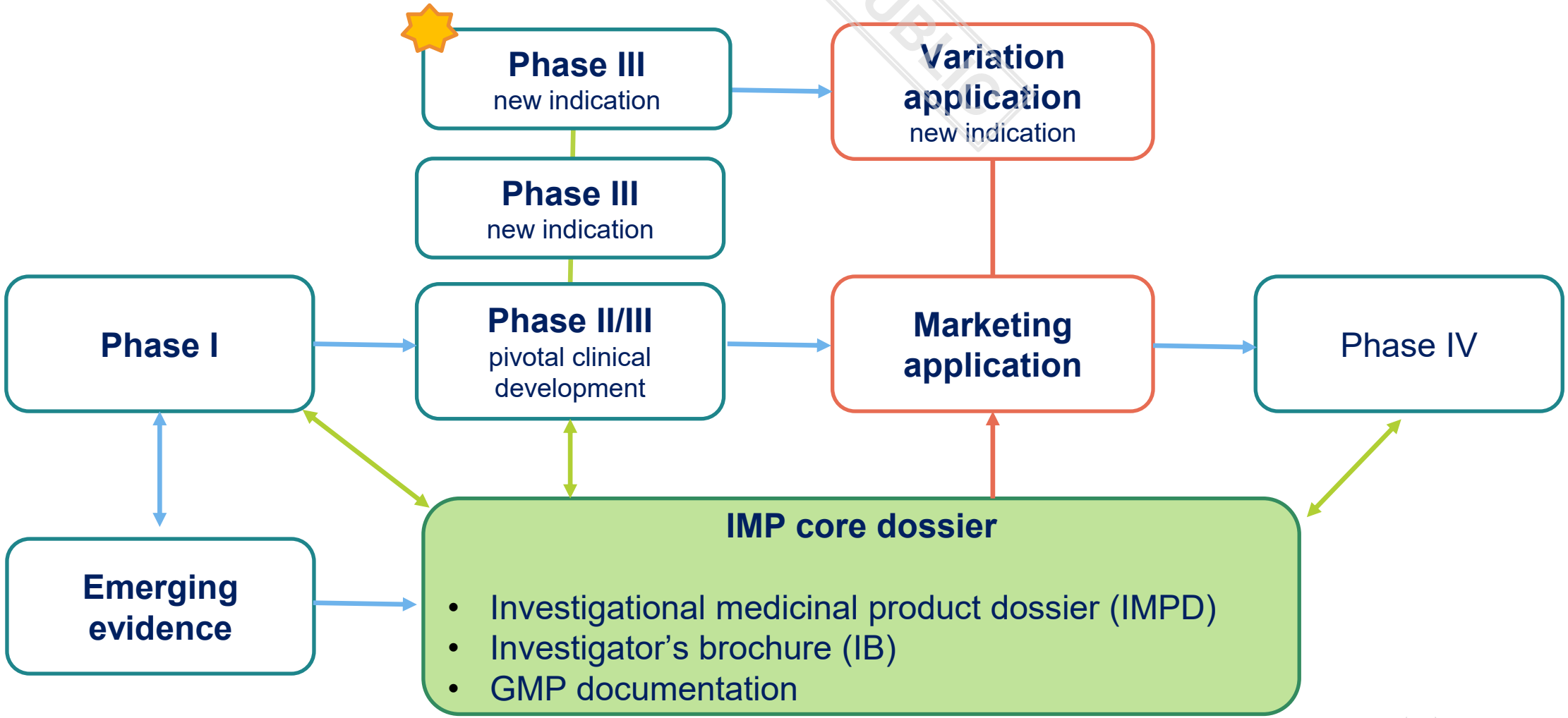
Establishment of an IMP Core Dossier

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Objectives:

- Enables re-use of evaluated product documentation across trials and sponsors, including academic sponsors
- Complements existing initiatives (e.g. IMP dossier on quality-only, Active Substance Master File- ASMF)
- Supports more efficient, consistent submissions, assessments and authorisations by reducing duplication
- Potential support for marketing authorisation applications (subject to further consideration)

IMP Core Dossier



non-commercial trial

European Commission

Article 27b – Maintenance and changes of the IMP Core Dossier

Article 27c – Procedural aspects related to the establishment and maintenance of the IMP Core Dossier

PUBLIC

Maintenance & changes of the IMP Core Dossier

PUBLIC

Key Changes:

- Changes to Core Dossier are established in relation to annual review, new information, new clinical trials application (CTA) submission
- Implementing regulation setting out the rules for submission, establishment, maintenance and cooperation between Member States

Objectives:

- Keep the Core Dossier current and suitable for purpose
- Avoid duplicate assessments across Member States
- Efficient re-use and lifecycle management of the Core Dossier
- Streamline authorisation and conduct of corresponding clinical trials



Annex I – Part I
Section Ga, Point 54a Core Dossier

European Commission

Section Ga, Point 54a IMP Core Dossier

PUBLIC

Key Changes:

- Describes the scope and content of the IMP Core Dossier
- Provides for the location of trial specific product information

Objectives:

- Common documentation across multiple trials, multinational settings

Annex I – Part I
Section Gb, Point 54b Possibility to refer to simplified IMPD
(including active substance master file)

PUBLIC

European Commission

Section Gb, Point 54b
Possibility to refer to simplified IMPD (including active substance master file)

PUBLIC

Key Changes:

- Quality information may be provided by reference using:
  - Active Substance Master File (ASMF), other accepted Quality Master Files, valid Certificate of Suitability (CEP), Certified Platform Technology Master File (where applicable)
- Sponsor and manufacturer's obligations

Objectives:

- Increased consistency and simplification
- Reliance on already evaluated documentation



Agenda Item: Regulatory Sandboxes and Use of Artificial Intelligence (AI)

European Commission



Article 27d – Regulatory sandbox

Regulatory sandbox: Paragraphs 1-3

PUBLIC

Key Changes:

- The regulatory sandbox for the CTR is a new provision
- Key features: testing innovative approaches in clinical trials in a controlled and time limited framework, under real-world conditions
- Scope: authorisation and/or conduct of trials, including use of Artificial Intelligence
- A specific sandbox plan would provide transparency over the CTR provisions that would be temporarily adapted or derogated from. The plan shall also identify the roles and responsibilities of sponsors, investigators, and manufacturers.
- Synergies with Regulation (EU) 2024/1689 (AI Act) and Pharma legislation sandbox

Regulatory sandbox: Paragraphs 4-9

PUBLIC

Key Changes:

- Eligibility criteria: innovative approaches that can not be fully accommodated under the current CTR framework and suitable for regulatory sandbox assessment
- Conditions:
  - Data robustness increased; Decrease length of the trial and increase efficiency; Enable new technologies and approaches for better treatment and healthcare
- Safeguards maintained:
  - Safety & well-being; Fundamental rights of participants; Data robustness; Integrity of the clinical trials
- Supervisory or corrective powers of the Member States Concerned are not affected
- Commission may establish a regulatory sandbox through implementing acts, with consultation of CTAG

Objectives:

- Provide a future-proof regulatory framework that can be adaptable to the fast scientific and technological developments, while protecting subjects' safety and data robustness



Article 27e – Use of Artificial Intelligence in Clinical Trials

Examples of use of AI in Clinical Trials

PUBLIC

By Regulators

- Preparation of the draft assessment report
- Translation of clinical trial documents in relevant language(s)
- Retrieve information from already approved clinical trials
- Preparation of a draft risk analysis and risk classification

By Developers

- Drafting of trial related documents
- Patient / sub-population selection in clinical trial
- Safety monitoring, including case processing
- Precision dosing
- Manufacturing process monitoring and control
- Digital Twins / predicting participant trajectories

Use of Artificial Intelligence in Clinical Trials

PUBLIC

Key Changes:

- Assessment of the use of the AI systems and models by sponsors
  - Related to patient safety and data robustness
  - In the context of a specific clinical trials
  - Information to be provided in the protocol:
    - Specific purpose for the use of the AI systems and models
    - Description of the process
- If AI system or tool qualifies as medical device: Combined studies process applies
- EMA mandated to develop guidelines on use of AI in clinical trials in cooperation with relevant Member States' groups

Objectives:

- Facilitate the uptake of AI in clinical research by providing predictability on the regulatory requirements for the use of AI in clinical trials

PUBLIC

Agenda Item: Vulnerable populations, protection of subjects (including data protection) and informed consent

European Commission



Article 10(6) – Specific considerations for vulnerable populations

Specific considerations for vulnerable populations

PUBLIC

Key Change:

- Weighing the harm of inclusion versus harm of exclusion for individuals belonging to vulnerable groups instead of automatic exclusion.

Objectives:

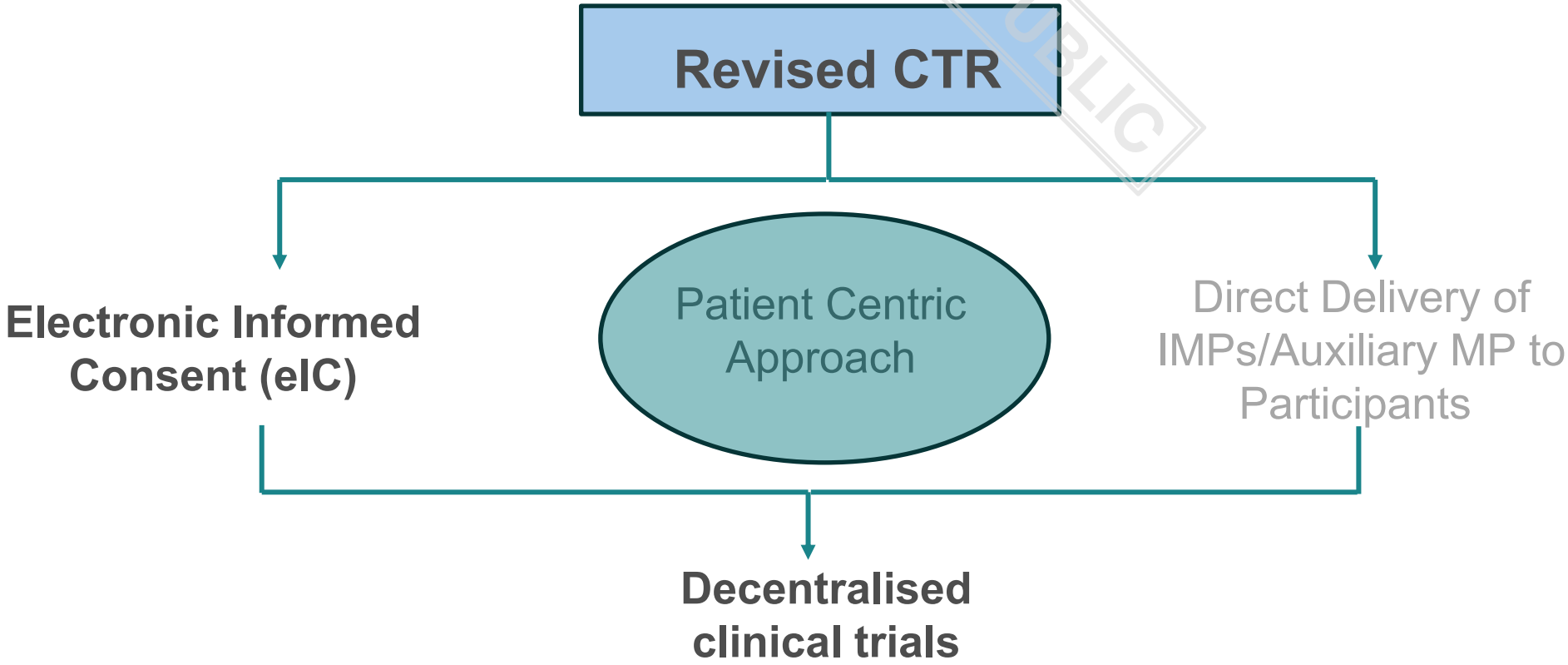
- Protect the rights of vulnerable populations, including minors, incapacitated participants, and pregnant or breastfeeding women, who may face a higher risk of harm or exploitation
- Align the Clinical Trials Regulation (CTR) more closely with the Declaration of Helsinki
- Promote the inclusion of vulnerable populations in clinical trials when the potential benefits outweigh the risks and burdens



Article 29 – Electronic informed consent

Accelerating Patient Centric Clinical Trials

PUBLIC



Faster Access -> Less Burden -> Better Recruitment

EU clinical trials more patient-centric, accessible and operationally efficient while maintaining participant protection and regulatory oversight

Electronic informed consent (eIC)

PUBLIC

Key changes:

- Provides EU rules and recognises eIC as a legally valid alternative to paper-based informed consent
- Establishes an EU framework for the use for electronic signature in compliance with relevant EU laws
- Improves transparency and regulatory oversight by requiring sponsors to describe the use of eIC or other decentralised activities in trial application

Objectives:

- Provide legal clarity and harmonised acceptance across the Member States
- Make clinical trials more accessible, inclusive and participant-friendly
- Strengthen clinical trial efficiency and resilience, by facilitating decentralised approaches
- Align with existing EU digital legislation

European Commission



Article 31 to 33 – Clinical trials on incapacitated subjects, minors and breastfeeding/pregnant women

European Commission

Clinical trials on incapacitated subjects, minors, pregnant/breastfeeding women

PUBLIC

Key changes:

- No automatic exclusion of incapacitated individuals or minors when the required data can be collected from other participant groups, while ensuring high ethical standards
- No automatic exclusion of women who become pregnant or breastfeeding during the clinical trial, while ensuring high ethical standards

Objective:

- Promote more equitable access to clinical trials and more representative clinical evidence through the appropriate inclusion of these underrepresented populations



Article 93 – Data protection

Simplifying Data Processing for Clinical Trials

PUBLIC

Key issues:

- **Legal uncertainty**
  - Divergent interpretation of the GDPR legal basis for processing personal data
  - Different interpretation of the roles and responsibilities of sponsors and investigators as data controllers
  - Inconsistent rules for access to clinical trial data to perform regulatory oversight
- **Impact on clinical trials**
  - Lengthy negotiations between sponsors, authorities and clinical research sites
  - Delays in clinical study initiation and participant recruitments
  - Increased administrative burden for multinational clinical trials

Simplifying Data Processing for Clinical Trials

PUBLIC

Key changes:

- **Data processing framework**
  - Single legal base for the data processing throughout the clinical trial lifecycle
  - Allows same controller to further process data for additional trials and scientific research
  - Clarifies data accessibility rules with regulatory authorities
- **Roles**
  - Clarifies the responsibilities of sponsors and investigators as GDPR controllers
- **Greater harmonisation across the EU**
  - Additional national measures on data protection in clinical trials will no longer apply

Simplifying Data Processing for Clinical Trials

PUBLIC

Objectives:

- Promote harmonised implementation of data protection rules across the Member States
- Support efficient multinational clinical trials by reducing administrative burden and legal uncertainty
- Facilitate scientific research and innovations
- Maintain a high level of protection for clinical trial participants personal data and support effective regulatory oversight



Agenda Item:
Conduct and supervision of a trial and manufacturing and import on an IMP

European Commission

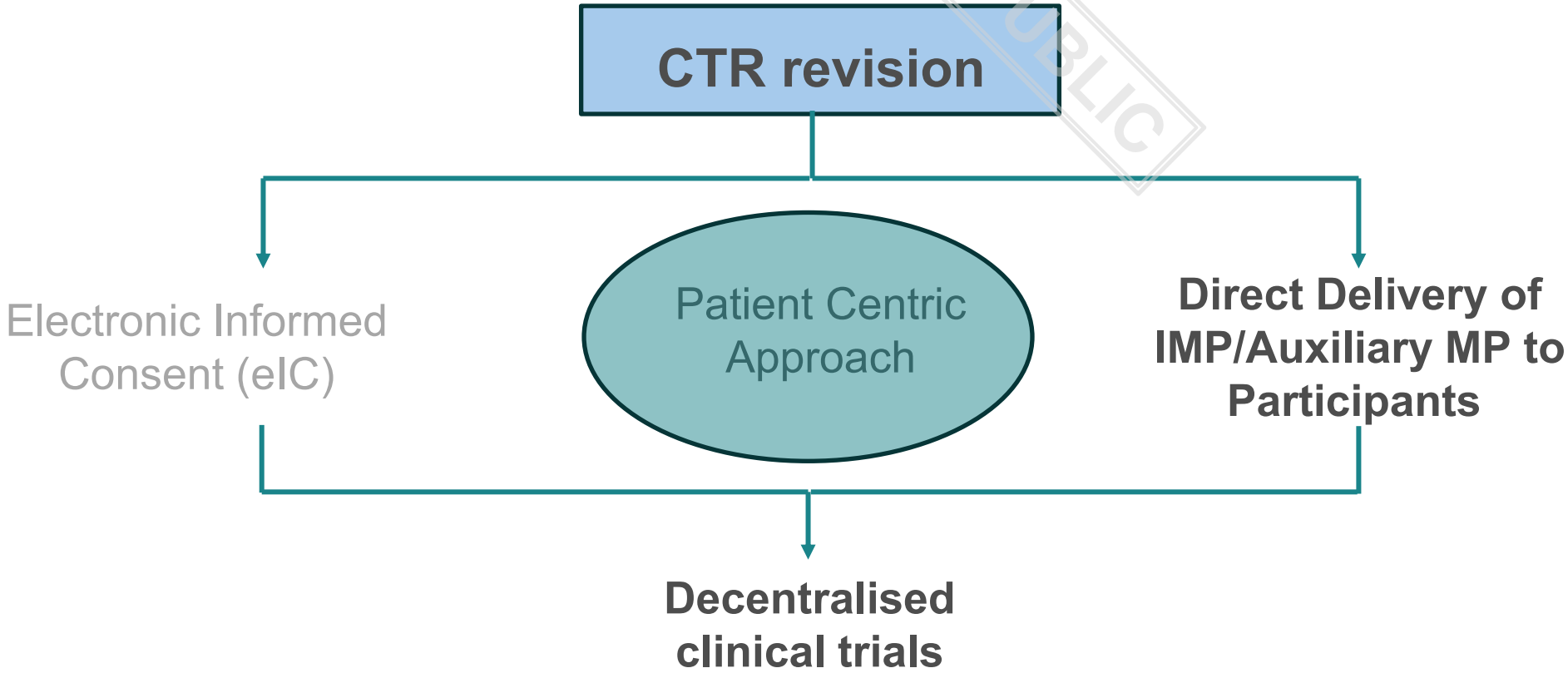


Article 50a – Delivery of IMP/AxMP direct to participants

European Commission

Accelerating Patient Centric Clinical Trials

PUBLIC



Faster Access -> Less Burden -> Better Recruitment

EU clinical trials more patient-centric, accessible and operationally efficient while maintaining participant protection and regulatory oversight

Direct delivery to participants

PUBLIC

Key changes:

- Introduces direct delivery to participants' home when authorised by the Member State
- Clarifies the responsibilities for sponsors, investigators and other parties involved in organising and managing home delivery
- Introduces harmonised EU requirements to ensure direct delivery is safe, well documented and consistently implemented across Member States

Objectives:

- Create consistent rules across Member States
- Support participant-centred clinical trials by improving enrolment and retention of participants
- Enable more flexible and resilient clinical trials, including decentralised approaches, while ensuring patient safety and appropriate oversight



Article 53(2) – Other reporting obligations relevant for subject safety

European Commission

Other reporting obligations relevant for subject safety

PUBLIC

Key Changes:

- Only third country inspection reports related to subject safety are to be submitted in EU Portal (CTIS)

Objectives:

- Regulatory review focused on safety-related information
- Reduced unnecessary administrative burden
- Better alignment with the core objective of proportionate approaches



Article 61 – Authorisation of manufacturing and import

Authorisation of manufacturing and import

PUBLIC

Key Changes:

- Introduction of general principles on how to ensure quality in the processes not subject to a manufacturing authorisation, such as re-packaging and re-labelling

Objectives:

- Provide predictability to sponsors on standards to apply, avoid fragmentation of implementation of provisions for re-packaging and re-labelling and give a set of reference principles for the inspectors



Article 63 – Manufacturing and import
Article 63a – Distribution

European Commission

Manufacturing and import distribution

PUBLIC

Key Changes:

- Introduction of the tools for Good Manufacturing Practice (GMP) inspections for IMPs: joint inspections, remote inspections and EMA inspectorate
- Introduction of a framework for the harmonisation of national requirements on the distribution of investigational and auxiliary medicinal products

Objectives:

- Provide consistent requirements to improve regulatory efficiency, ensure consistent CTR implementation across the Union, and enhance predictability for developers, particularly for decentralised and cross-border clinical trials.



Article 78 – Member State inspections

Member State inspections

PUBLIC

Key Changes:

- On site or remote Good Clinical Practice (GCP) inspections, including unannounced inspections
- Joint inspections and delegation of inspections to the EMA on request from the NCAs
- GCP inspection reports to be issued within the agreed timelines for marketing authorisation application-related inspections or within 90 days of the inspection, whichever is shorter

Objectives:

- Provide consistent requirements, to improve regulatory efficiency, optimisation of inspection resource
- Improve compliance and trial outcomes by strengthening of GCP inspections



Agenda Item: Enforcement and Governance

European Commission



Article 79 – Union controls

Union controls

PUBLIC

Key Changes:

- Clarification of the scope of the Union Controls to ensure that for the purpose of marketing authorisation applications, clinical trials conducted outside the EU are based on the GCP and ethical principles equivalent to those established in the CTR
- Detailed description of the process leading to the submission of the final Union Control report in EU Portal (CTIS)

Objective:

- Efficient conduct of union controls ultimately ensuring that Member States have the necessary measures in place for a proper implementation and application of the Clinical Trials Regulation



Article 79a – Obligations as regards Union controls

Obligations as regards Union Controls

PUBLIC

Key Changes:

- Sets out the conditions for the Commission to conduct Union Controls in cooperation with MS

Objectives:

- Ensure that Member States have the necessary legal base in place for a proper implementation and application of the CTR
- Ensure that increased reliance on Member States is supported by effective oversight
- Safeguard consistent performance and trust in the EU system

Article 83 – Competent authorities and ethics committees

Article 83a – Communication and coordination between competent authorities and between ethics committees

PUBLIC

Competent authorities and ethics committees

PUBLIC

Key Changes:

- Rights and responsibilities of the national contact point for the practical implementation of the CTR are strengthened
- Increased responsibility to the Member State for ensuring proper communication between national competent authority and the ethics committees within their Member State

Objectives:

- To have a clear representative at national level with adequate capacity to ensure application of the CTR



Article 85 – Clinical Trials Coordination and Advisory Group

European Commission

Clinical Trials Coordination and Advisory Group (CTAG)

PUBLIC

Key Changes

- CTAG member with a 3-year term renewable once and alternate (different to national contact point)
- New roles for CTAG to ensure strategic steering on the application of the CTR and the clinical trial ecosystem
- CTAG to provide recommendations and opinions on clinical trials and endorse guidance related to the application of the CTR, including AI
- CTAG to provide a recommendation before the setting up of a regulatory sandbox

Objective:

- A reinforced CTAG creates stronger EU-level coordination and oversight



Agenda Item: Final Provisions

European Commission

PUBLIC

Article 97 – Review

Article 98 – Transitional provision

Article 67(3) of the BTA -- Entry into force and application

Transitional provisions and review clause

PUBLIC

Key changes:

- Transitional provision: new provisions applicable to procedures initiated from the date of entry into application of the BTA
- Review clause: regular review, introduction of a KPI

Objectives:

- Ensure predictability and smooth transitioning of the new CTR provisions
- Support impact monitoring for evidence-based policy decisions

Date of application

PUBLIC

Application Dates (see Art. 67(3) of the BTA)

- Immediate (20 days): all provisions, unless deferred
- 6 months: IMP Core Dossier and related provisions
- 9 months: authorisation of public health emergency-related trials and combined studies and related provisions

Objective:

- Ensure predictability and smooth transitioning of the new CTR provisions



Article 98a – Development plan for the EU Portal and database

European Commission

Development plan for the EU Portal and database

PUBLIC

Key Changes:

- EMA responsibilities in relation to EU Portal (CTIS)
- Revised IT development plan to the EMA Management Board within one month of the BTA entering into force
- All required system functionalities by application date
- Key milestones and timelines to be published by the EMA

Objectives:

- Ensure that EU Portal (CTIS) is a reliable, efficient and future-proof regulatory infrastructure
- Create trust and predictability in all stakeholders