Reducing review timelines to 60 days: enhancing competitiveness through faster CTA approval

MSG AG September 2025

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What is the problem?

- **The time needed for CT approval in the EU exceeds 110 days** compared to 30 - 60 days in other global regions → barrier for attracting trials
- **Key factors for observed longer timelines include:**
  - Inconsistent submission requirements across Member States (MSs)
  - Misalignment between Part I and Part II reviews
    - Multiple document updates
    - Delays in study start due to conditional approvals and required substantial modifications
  - Complexity of review process and CTIS limitations

Efficiencies need to be implemented to allow faster review while ensuring patient safety and high-quality data generation

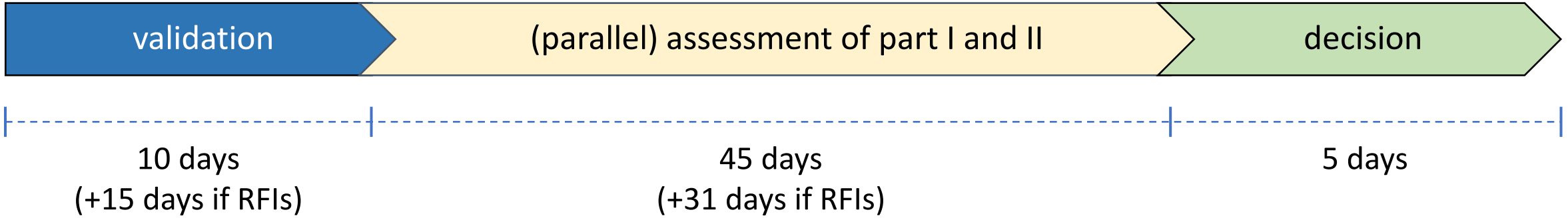
Shortening approvals is key to enhance EU competitiveness

Encourages Sponsors to (continue to) conduct clinical trials in the EU, recognised for its valued healthcare infrastructure and world-leading academic and research institutions

Ensures EU patients are not excluded from global multi-country trials and contributes to potential faster enrolment

Contributes to more efficient use of (limited) resources

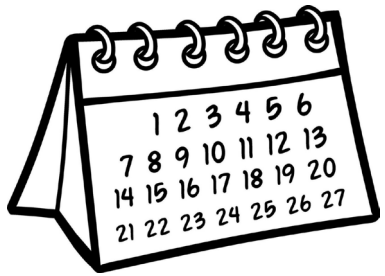
CTR timelines allow for **60 days** approval and up to **106 days** in case of a request for information (RFI)



Release of Part I RFI is *scheduled* in the CTIS system

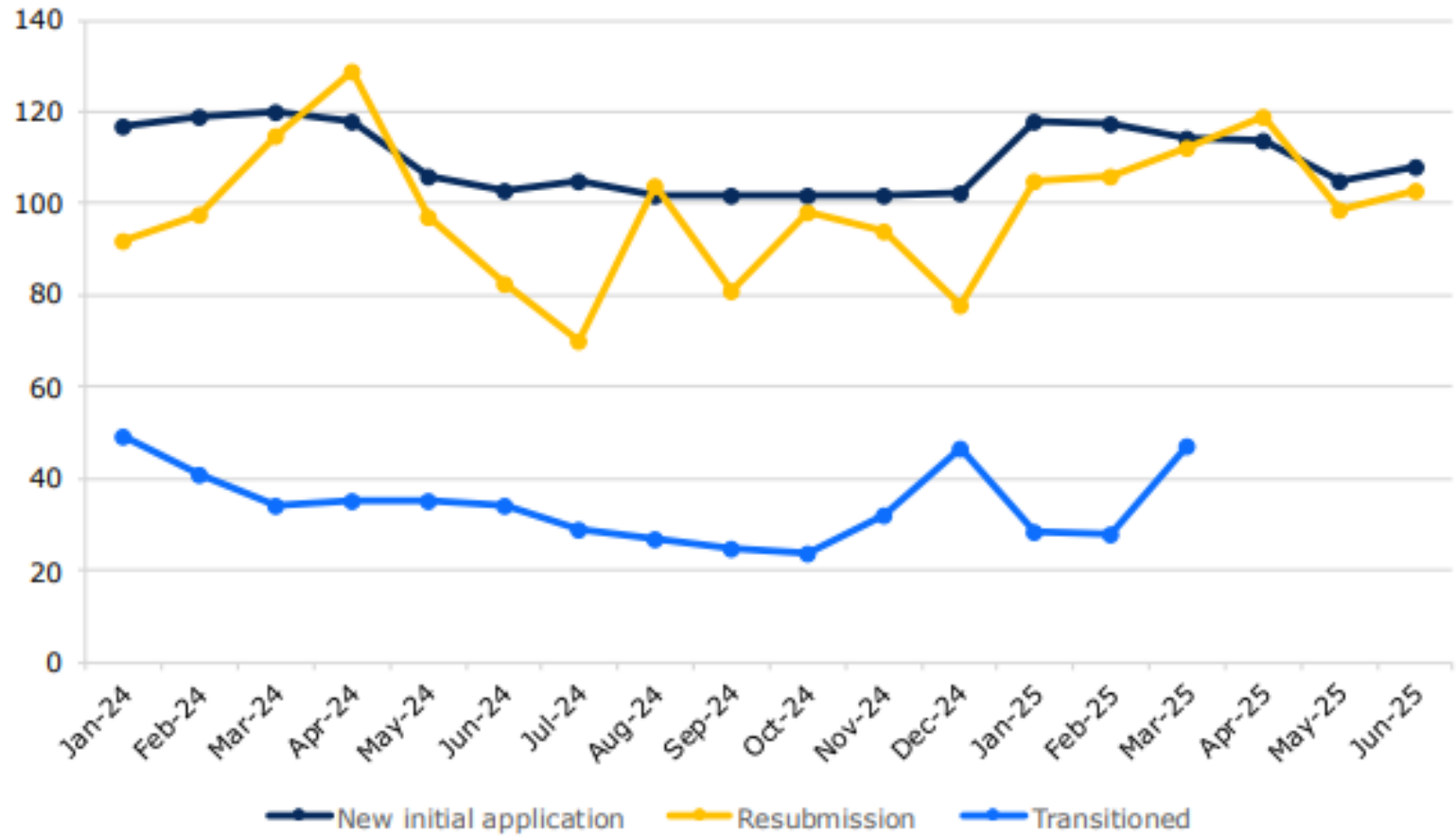
RFIs for Part II can be issued *anytime* during the assessment

These timelines represent **maximum limits** that should not necessarily be always used in full



Currently observed metrics

Median time per new initial application/ resubmission and transitional trials from submission of initial clinical trial applications to decision



[Report to monitor the European clinical trials environment (April - June 2025)]

Efforts to expedite timelines across the EU

Several EU countries have launched pilots or established internal processes to reduce approval timelines for (certain types of) mono national CTs, e.g. Germany, Spain, Denmark, Belgium, Austria, Sweden. As part of these (pilot) proposals, they stick to the minimum or even reduce the established review timelines.

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Authorities acknowledge the need to accelerate reviews and are taking steps in that direction

Implementation of such processes across MSs is inconsistent

These practices should be leveraged to avoid further fragmentation and ensure faster multinational clinical trials approvals

Actionable proposals to reduce timelines

Risk-based approach to review and reliance

- focus on high risk-trials
- restrict RFIs to critical issues
- reduce assessment phase for CMS

Coordination of part I and II reviews

- avoid unnecessary RFIs
- harmonisation of requirements
- definition and alignment of roles and responsibilities of ECs & NCAs

Shorten unnecessarily long steps

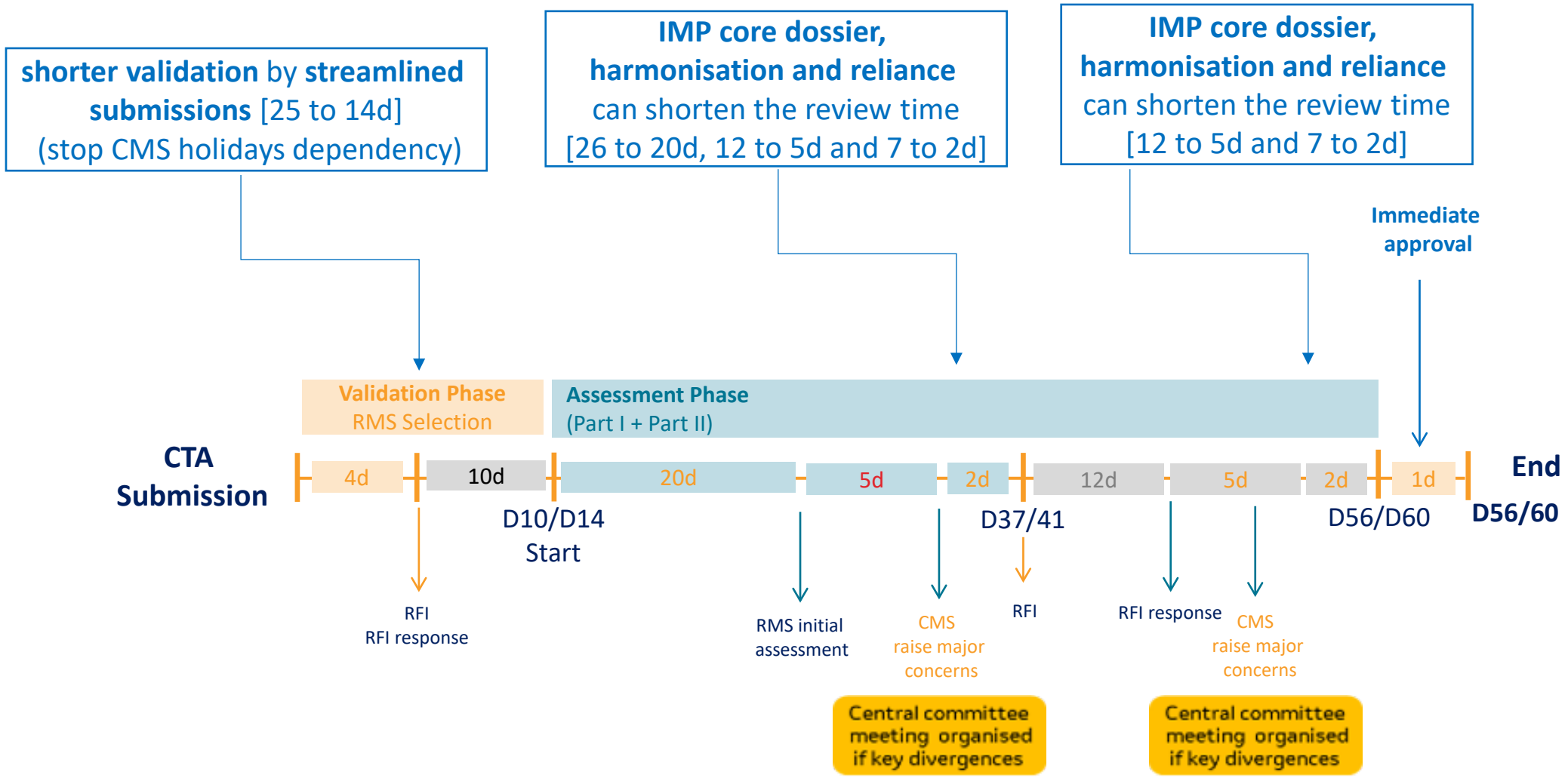
Remove extension of review deadlines for given class of products

Expedite review timelines for 'simple/administrative' SMs (including to implement conditional approvals)

Enable parallel submission of SMs (not inter-related)

Core-dossier model, CTIS improvements and convergence with other regulations

How an approval in 60 days may look like?



Enabling outcomes

- Can 60-day approvals be enabled within CTR, through guidance and best-practice sharing?
- Is it possible to empower the RMS to coordinate Part I and Part II reviews? Is there room for more central coordination?
- Would a risk-based approach to review and reliance opportunities increase efficiency in review?
- Can we agree on criteria to define trials that should always undergo a 60-day review?

Thank you