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Use of raw data in medicine evaluation

17th Industry Stakeholder Platform on the operation of Centralised Procedure for human medicines | 20 November 2026

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Upcoming legislative changes in the EU

New Pharmaceutical Legislation

Patient-level data

Individual patient-level data (“raw data”) become mandatory for most initial MAAs in the centralised procedure.

Scope: initial full applications, hybrids and bio-hybrids.

Exceptions: generics, biosimilars and well-established use.

In vivo toxicology data

Raw data for all in vivo toxicology studies will also be required to be submitted.

Requirements and guidance

Annex II and guidance will specify study types, data standards and formats.

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Submission of **clinical study data**

Follow up on the EMA-CHMP proof-of-concept clinical study data pilot

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Table of contents

1 **Pilot status update**

2 **Preparing for NPL implementation**

3 **Interaction with Industry and next steps**

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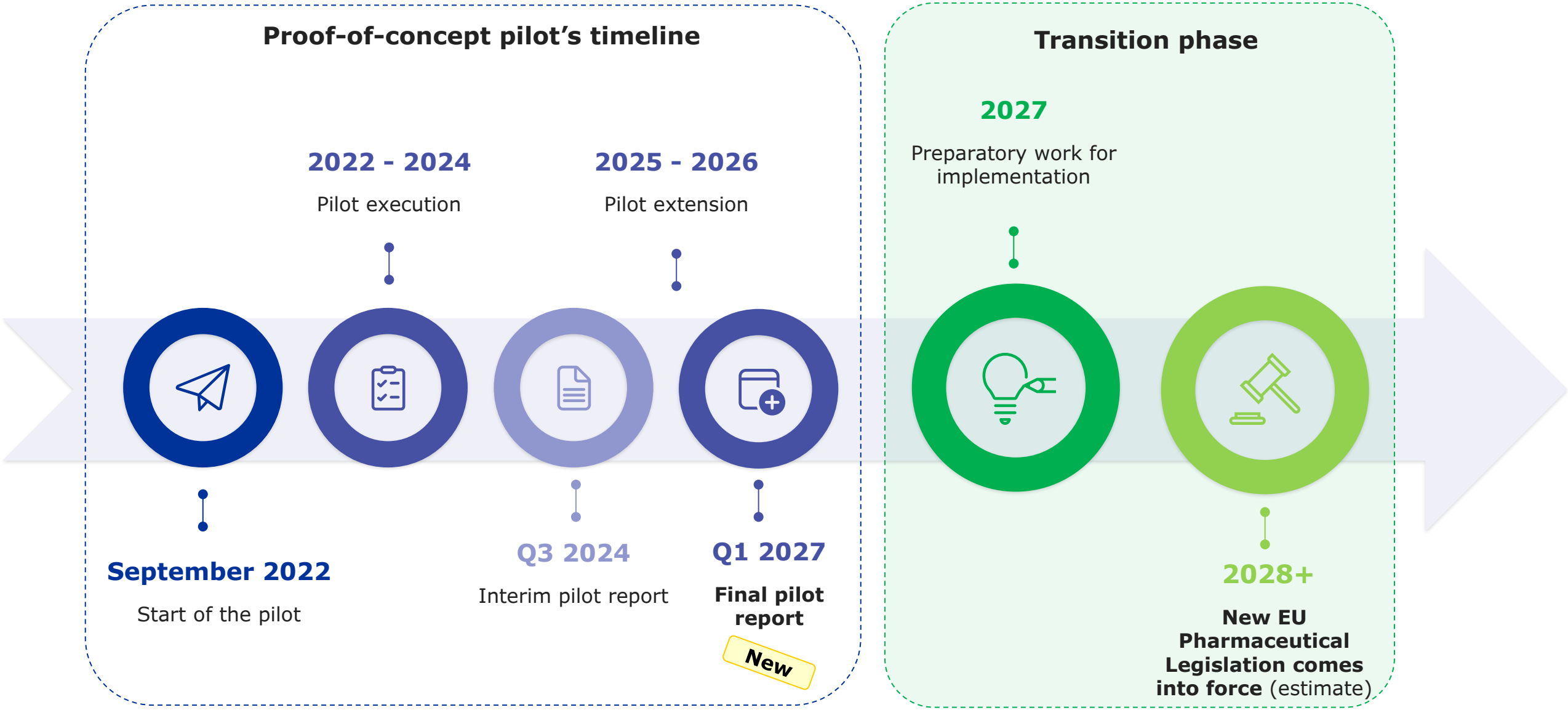
Clinical study data initiative timeline



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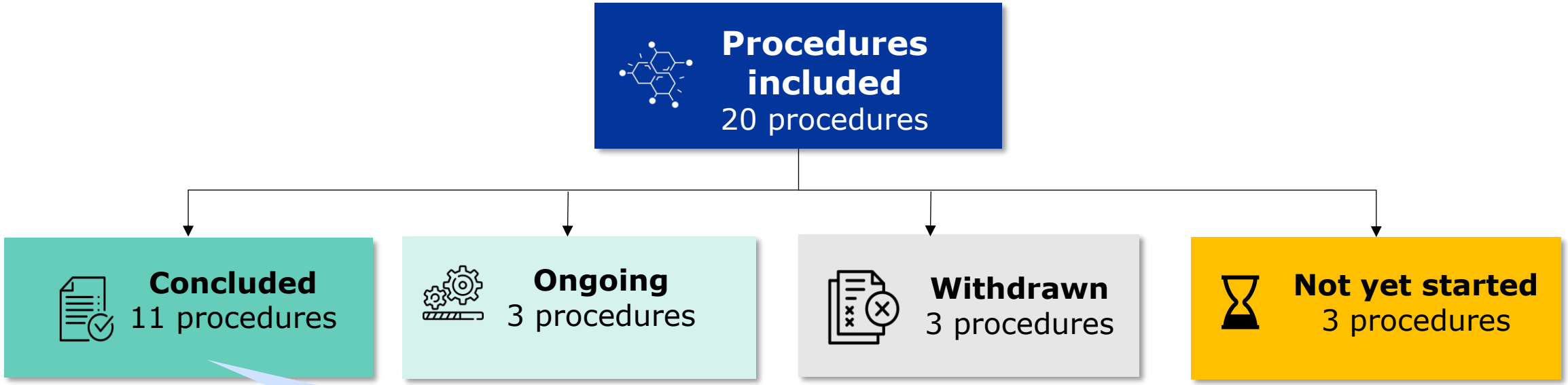
Pilot current status

Information of procedures included in the pilot since 2022



*Additional procedures are currently being evaluated for inclusion and voluntary submission of CSD will still be **encouraged after pilot closure until NPL comes into force.***

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Participants' pilot feedback

New

Positive feedback from participants
Feedback consistent with the findings of the interim pilot report

Access to and analysis of clinical study data **enhanced benefit/risk assessments** and supported **more informed regulatory decisions.**

Clinical study data analysis made **GCP site selection more robust, objective, and transparent.**

Availability of data improved the **quality and clarity** of LoQ/LoOI/RSI.

New

Repeated participation in the pilot led to greater **efficiency and process familiarity.**

Collaboration among assessors and data analysts **added significant value to the process.**

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From pilot to future implementation

1. **Governance and ways of working**
2. **Procedural aspects, guidance and reporting**
3. **Technical aspects and data governance**
4. **Capacity and capability**
5. **Implementation readiness and stakeholder engagement**

JOINT – COLLABORATIVE EFFORT

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Industry Group focusing on Clinical Study Data – est. 2022

- Intensify collaboration with Industry
- Promote dialogue
- Opportunity for members to share their views on specific pilot's aspects
- Guidance for Industry
- Application of EMA's transparency policy



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Reset industry engagement around focused projects

CURRENT MODEL

Industry Group focusing on Clinical Study Data

Anchored in the Industry Stakeholder Platform on the operation of the centralised procedure

Purpose fulfilled: supported dialogue during the PoC pilot

Current limitation:
discussions stalled as the group could not converge on a collaborative way forward and broadened into transparency matters

Close the group with pilot closure

PROPOSED TRANSITION

FUTURE MODEL

Targeted collaboration around defined topics and deliverables

1. Time-bound projects with a clear question, scope and output
2. Bring together the right policy, regulatory and technical expertise
3. Use established technical communities such as PHUSE and CDISC where relevant
4. Maintain transparency and broader stakeholder balance through appropriate EMA channels

Flexible • technical • outcome-oriented



RECOMMENDATION | Conclude the standing group at pilot closure and move to fit-for-purpose collaboration with Industry on specific implementation topics and projects.

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Take home messages

Q1 2027

EMA-CHMP clinical study data pilot closes

Pilot outputs

Final pilot report

Implementation roadmap including guidance to be developed

Voluntary submission continues during 2-year transition period

Until NPL enters into force (end of 2028)

Open to expressions of interest

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Submission of **non-clinical data**

Follow up on SEND pilot

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Agenda



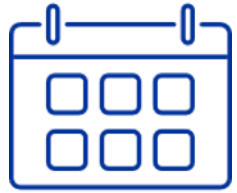
Update on the SEND proof-of-concept study



Share the key learnings so far



Introduce the new requirement on raw non-clinical data from 2028



Present the next steps and collect industry feedback

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SEND proof-of-concept study: where we are

- **January 2024 - PoC started**: to assess whether SEND improves the quality, consistency and efficiency of non-clinical assessments.
- **May 2026 - PoC objective achieved**: Submissions containing >5 SEND data packages received from 15 applicants.
- **Voluntary submissions continue**: to gain experience with multiple datasets per application and progress towards the original target of up to 20 applications.

43%
of applicants submitted SEND datasets (47 of 110)

285
studies received, mostly repeat-dose toxicity

>75
assessors from 8 countries have access to visualisation software

57%
did not submit SEND datasets, mainly biologicals

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Key learnings so far

Assessment

- Facilitates comparison of toxicology data across multiple studies
- Complements the CTD and study reports with direct analysis of study data

Assessors

- Training required to make full use of the visualisation software
- Request to extend access to all non-clinical toxicology assessors in network

Applicants

- Positive feedback from industry - reuse of FDA-compliant SEND packages limits additional burden
- Need to clarify whether SEND datasets qualify as documents under AtD (policy 43)

Technical

- Data receipt, conversion and storage processes require further optimisation for scale-up

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Next steps and questions for industry



Next steps

PoC outcome: Expected 1H 2027

Voluntary submission: Continues until new requirements apply

Guidance: Develop raw data submission guidance

Feedback: Your input is welcome



Questions for industry

Legacy studies: What are the main challenges in generating SEND datasets retrospectively?

Implementation: What practical or technical challenges are foreseen?

Preparation: What would help to prepare for mandatory SEND submission?

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