EMA
EUROPEAN MEDICINES AGENCY

EMA SEND Proof-of-concept study

15th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicine

28 November 2025

Presented by Ciska van Doesum

Background

Proof-of-concept study initiated in 2024 to evaluate if non-clinical information in SEND format will improve **quality, consistency** and **efficiency** of assessments

Continues until 10-20 applications have included SEND datasets as part of the iMAAs submitted to EMA

Expected benefits

- Improved and more consistent assessment **quality**
- More **science driven** & less **data driven** questions to Applicant
- **Fewer non-clinical rounds** and/or **faster completion** of the review of the non-clinical dossier

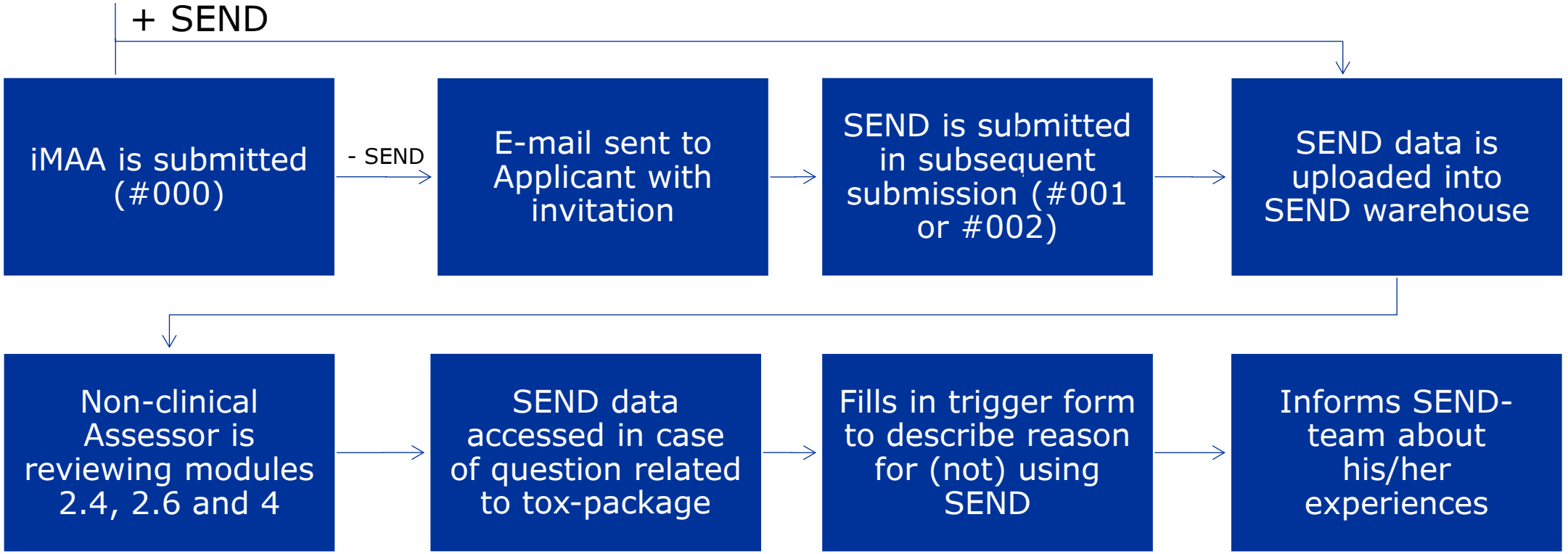
Use	Data exchange standard	Regulatory agency	Date support start	Date requirement start
Animal study datasets	3.1	CDER	Aug 2017	March 2019
		CBER	March 2021	March 2023
		EMA	Jan 2024	N/A - voluntary

Objectives

Allow EMA reviewers

- Access, review and visualise study data electronically to supplement pdf-materials submitted by sponsors
- Become familiar with visualisations designed for use by regulators
- Demonstrate and assess the benefits of data visualization including expedited review, outlier investigation, identification of patterns & trends, and cross-study comparisons
- Quantify/qualify potential time savings in data review process
- Provide a mechanism for capturing key relationships and sharing visualisations with other scientists
- Help familiarise reviewers with the SEND standard

Process-flow



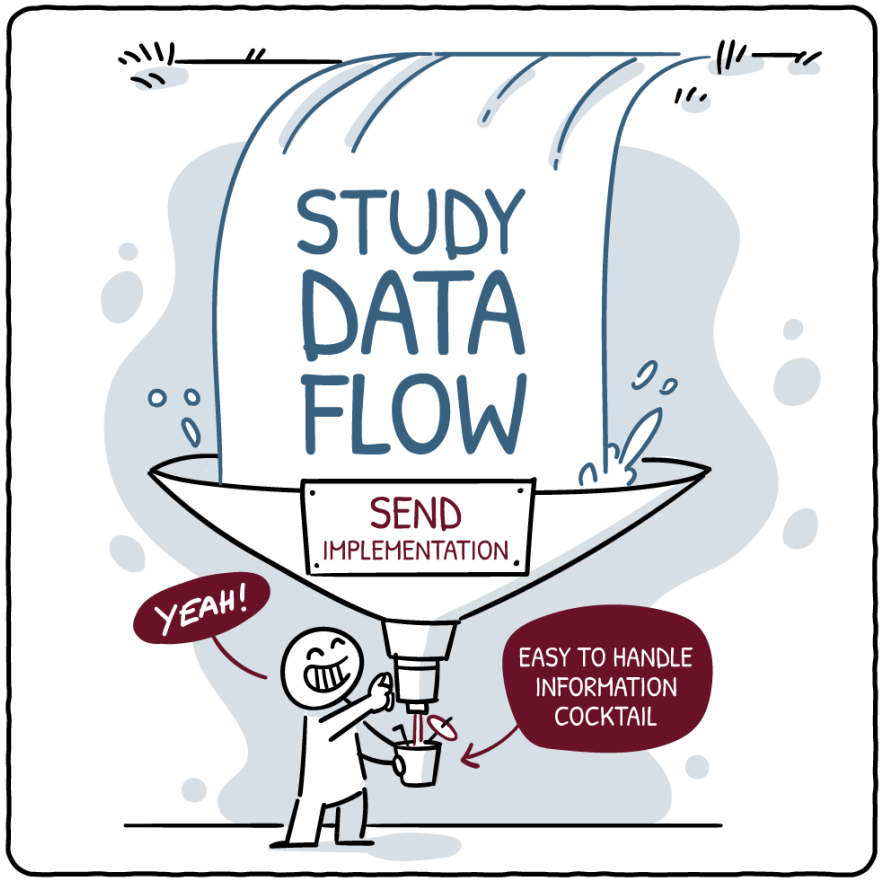
Overview of activities applicants

January 2024: Applicants are encouraged to submit their (already available) non-clinical SEND data packages as part of their eCTD MAA submission

- 3/47 (6%) of iMAA applicants submitted one or more SEND data packages

January 2025: Applicants that did not submit SEND with their (initial) MAA submission are contacted with a request to submit in a subsequent submission

- 1/49 (2%) of applicants submitted their SEND data package as part of their initial eCTD MAA submission
- 26/49 (58%) of applicants submitted one or more SEND data packages as a follow-up submission
- 22/49 (40%) did not submit SEND data (mainly biologicals)



https://www.toxicology.cc/html/news-2021-03.html

Overview of activities Applicants (2/2)

New active substances - Chemical

#SEND studies	# of submissions
0	12
1-4	11
5-9	5
≥10	6
Total	**34**

New active substance – B-Mab/Bio/Vaccine

#SEND studies	# of submissions
0	12
1-4	2
5-9	1
≥10	0
Total	**15**

Overview of activities EMA

- Loaded >180 studies into SEND Explorer Warehouse environment
- SEND data augmented with Application ID, Rapporteur, and Co-Rapporteur by EMA system administrator
- Access granted to 69 reviewers from 6 countries
- Trainings for assessors organised on
  - single-study functionality
  - multi-study function
  - hands-on workshop

Overview of activities of non-clinical assessors

27 submission received with SEND data in 2025

- 15/27 have been included in proof-of-concept
- 5/27 Applications not included as rapporteur & co-rapporteur team not participating
- 7/27 Applications in first round of assessment (submitted in Aug-Oct)

Future steps

Proof-of-concept phase completed at end of 2025 and results will be reported in 2026

From January 2026 onwards

- Assess impact of new Directive of EU pharma legislation
  - Article 6 includes “The documents and information concerning the results of the pharmaceutical and non-clinical tests and the clinical studies referred to in Annex I shall be accompanied by detailed summaries in accordance with Article 7 and supportive raw data.”
- Continue stimulation of voluntary submission of SEND data by Applicants
- Continue support/training of non-clinical assessors to gain experience with using SEND data visualisation during assessment
- Extend access to SEND visualisation software and training to other interested non-clinical assessors
- Feedback/suggestions remain welcome on send@ema.europa.eu

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Thank you

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