EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

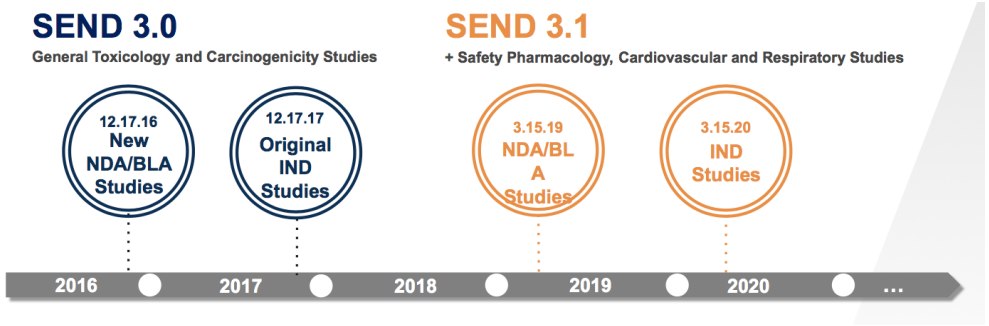
New in 2024: opportunity to submit SEND data

11th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

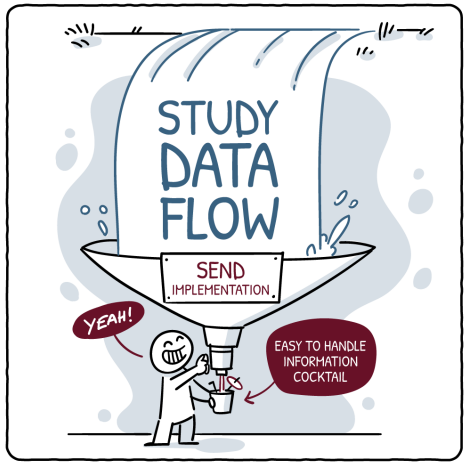
Presented by Corinne de Vries, head of Translational Sciences; Scientific Evidence Generation Department, Human Medicines Division

What is SEND

- **S**tandards for **E**xchange of **N**on-clinical **D**ata
- Initiated by FDA to improve **predictability, consistency** & **efficiency** of review process
- **Required** by FDA since December 2016
- SEND has been highlighted as an important tool **in EMA's regulatory science strategy 2020-2025**



What will happen in 2024



- Proof-of-concept study: does SEND support
  - improved and more consistent **assessment quality;**
  - more **science driven, relevant** questions to Applicant;
  - **faster completion** of the non-clinical dossier review?

- Applicants are encouraged to submit SEND data packages, in addition to the eCTD format, as part of their MAA submission
- EMA will evaluate & publish the impact –qualitative and quantitative - on assessment, with recommendations

Any questions?

Further information

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