HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Challenges related to recording, measuring, characterising, analysing and improving ADR data quality

A view from the end of the process

Presented by Thomas Paternoster-Howe 1 March 2024
EMA TDA-HCD

Summary

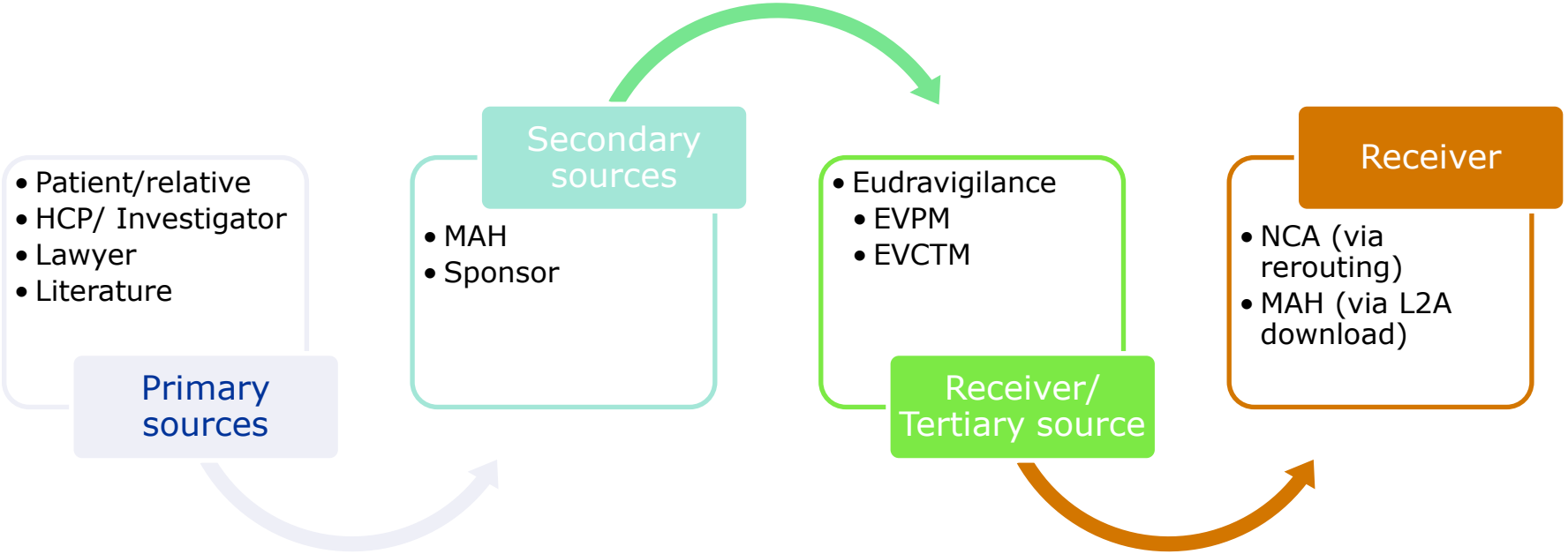
EMA’s position in the ADR data pipeline

Challenges associated with being near the end of the pipeline

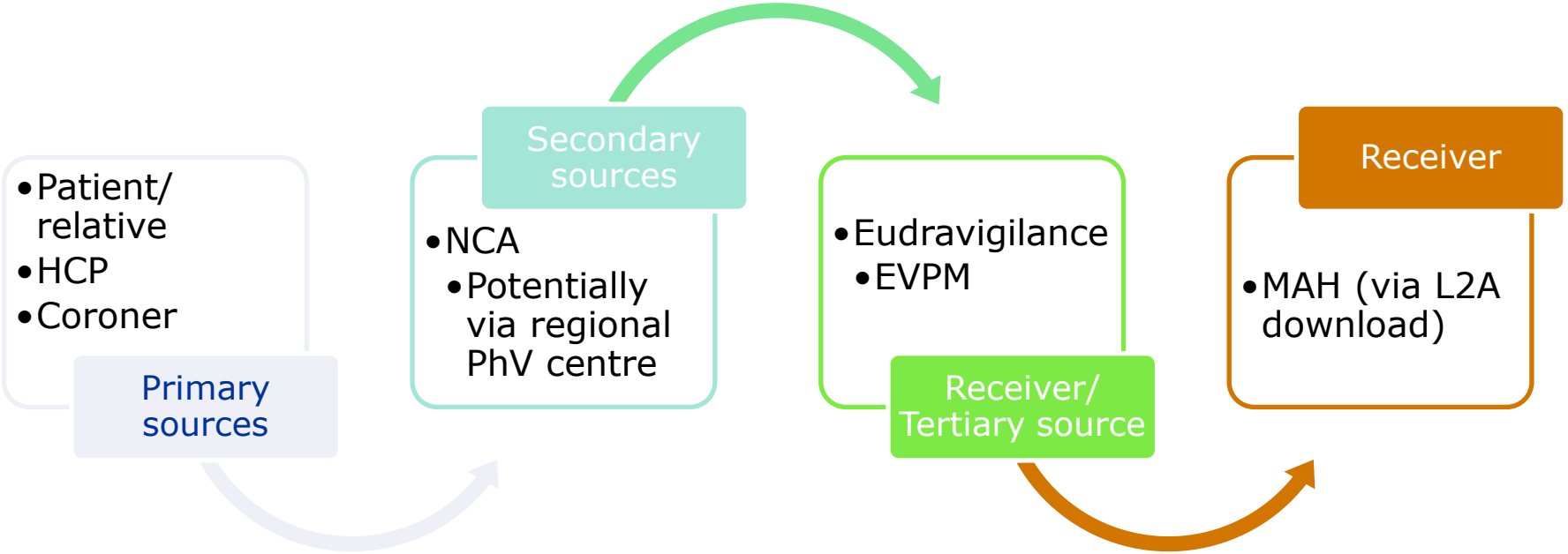
Challenges related to recording, measuring, characterising & analysing ADR data quality

Challenges related to improving ADR data quality

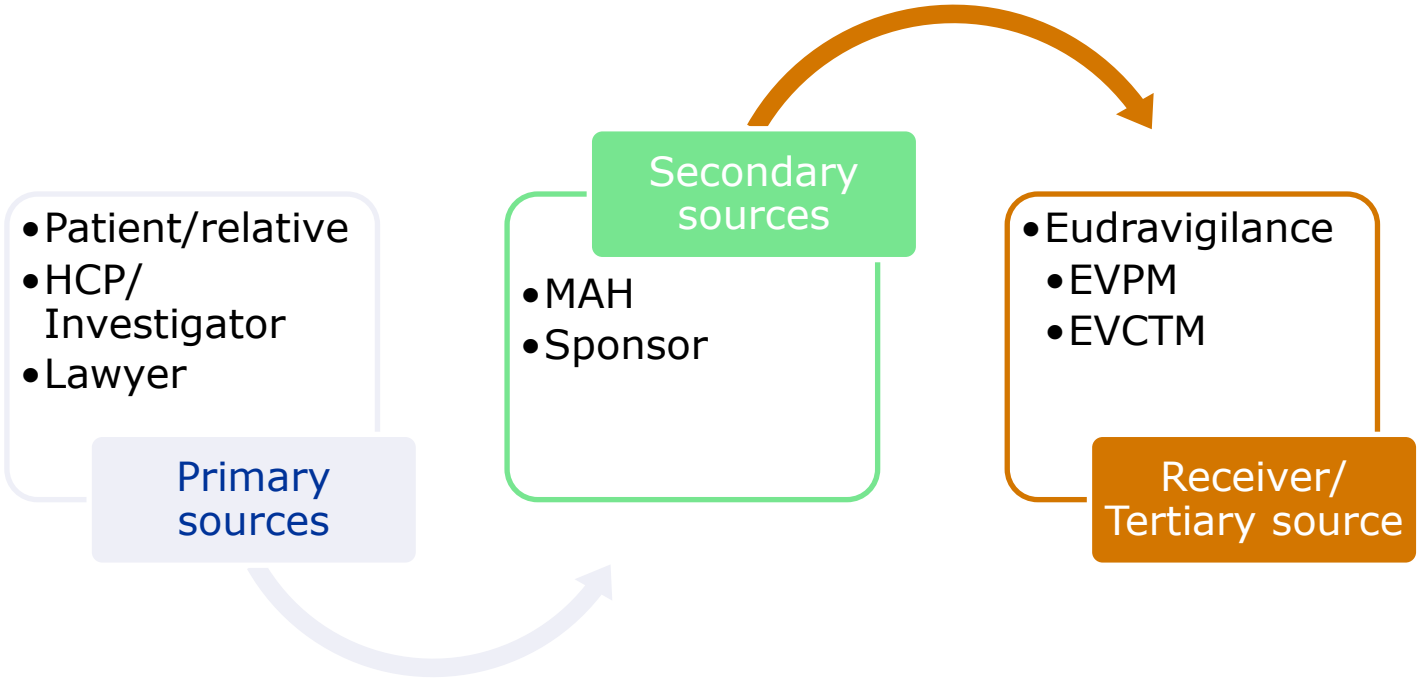
ADR data pipeline – EEA ICSRs via MAHs



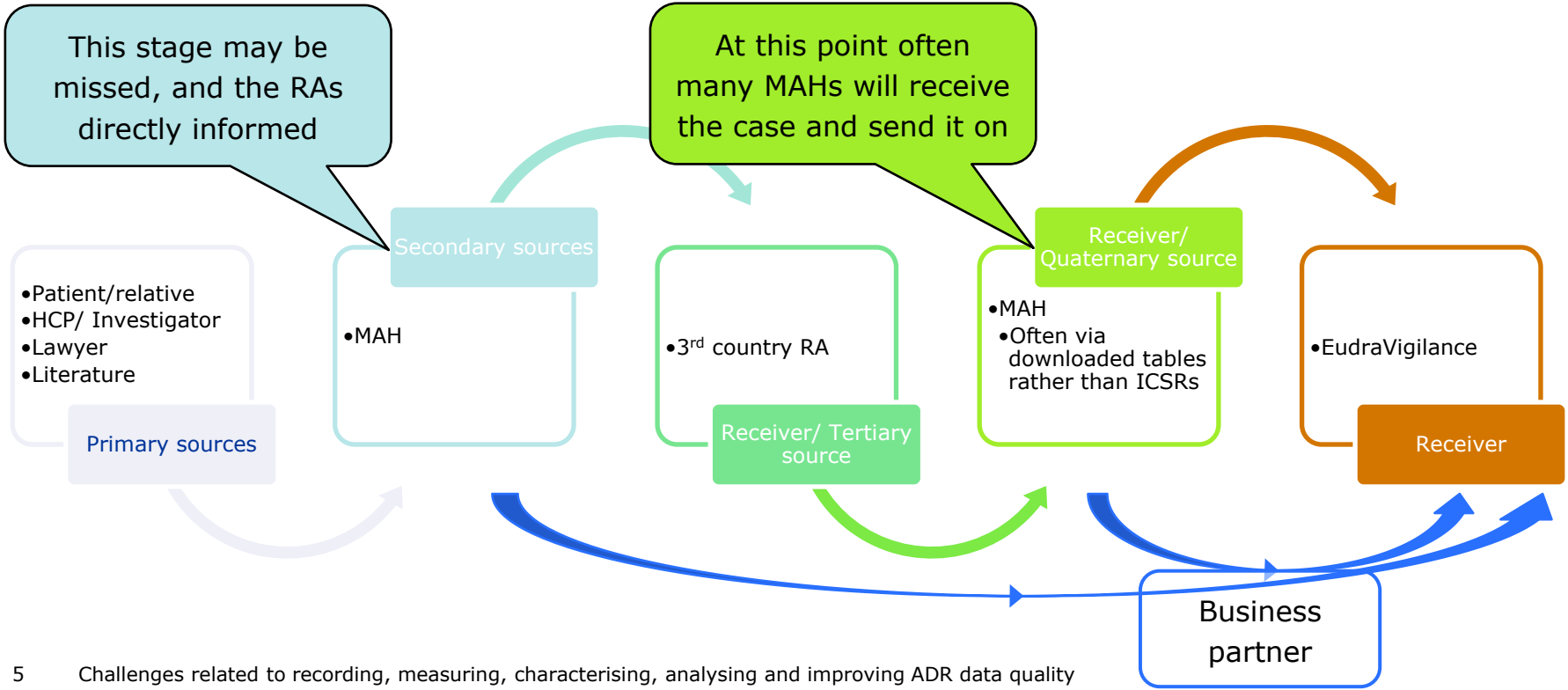
ADR data pipeline – EEA ICSRs via NCAs



ADR data pipeline – non-EEA ICSRs from originating MAH



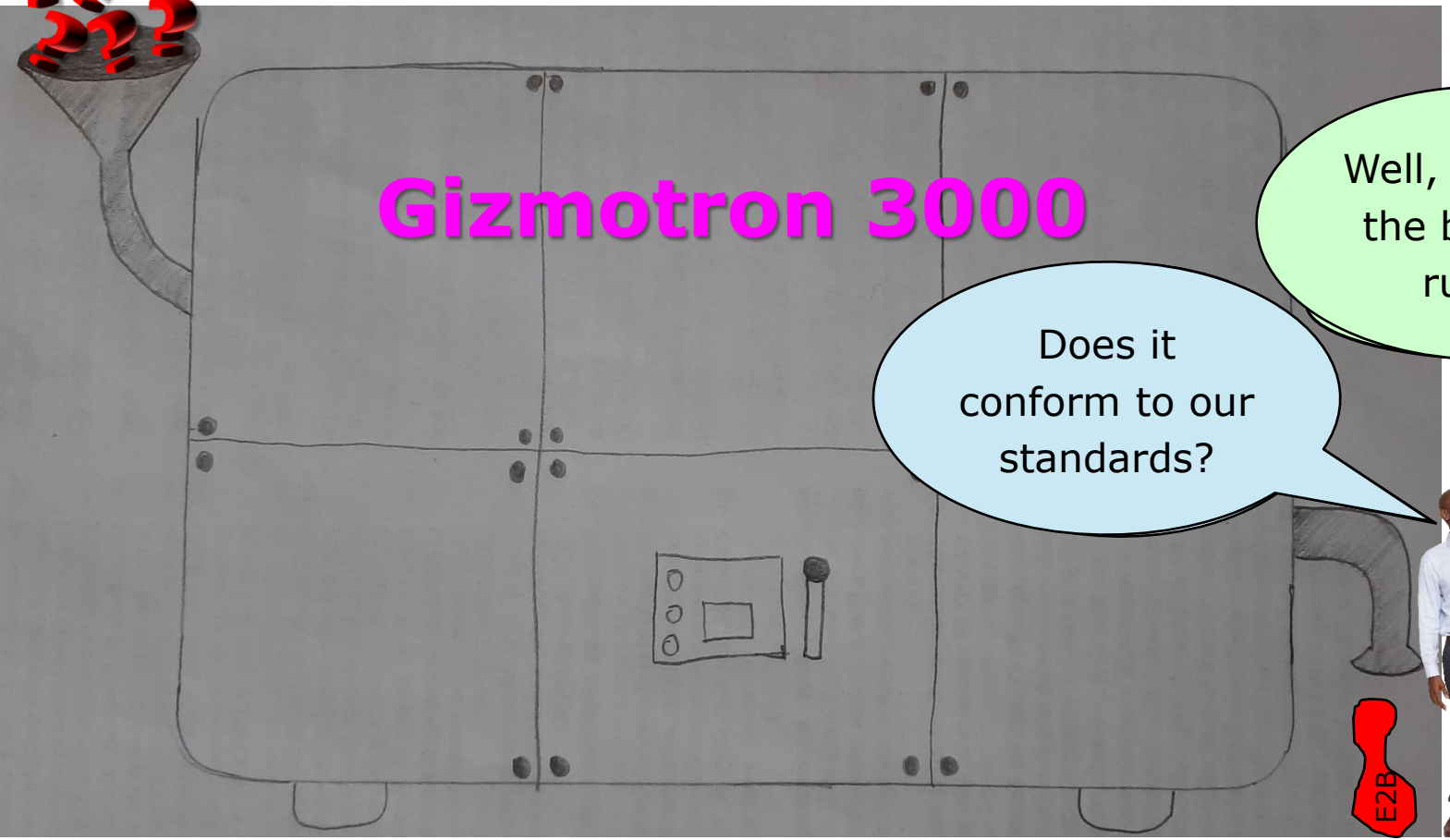
ADR data pipeline – non-EEA ICSRs via secondary MAH(s)



Challenges associated with being near the end of the pipeline

When EMA receives an ICSR, there are various unknowns:

- What was the source information?
- Is all the reported information in the case?
  - Would the sender have been permitted to include all the reported information?
- Was it accurately entered?
- Was it correctly structured?
  - The basic fields must be structured to pass the business rules, but that does not mean that the structuring correctly reflects the information in the case, nor that it makes a valid case
- How many copies of the same ADR are in different cases?



Challenges related to recording, measuring, characterising & analysing ADR data quality

The scale of pharmacovigilance can make it difficult to comprehensively assess data quality

- EV receives ~10,000 ICSRs/day
- ~5,000 unique senders of ICSRs per year

How best to prioritise assessments?

- Random selection?
- Number of cases/annum?
- Risk-based?
- Targeted to coincide with other measures?

Challenges related to recording, measuring, characterising & analysing ADR data quality

The quality of ADR data can be characterised in various ways:

- Completeness
  - Is everything entered that should be? Is more data always better? How many tests is too many?
- Accuracy
  - Does the case reflect what was reported? What if what the verbatim reported term was unhelpful bordering on useless?
- Structuring & unstructuring
  - Was the data broken down into each structured field? Or was a beautiful long essay crafted lovingly to tell the story of the ADR in the narrative with only a bare minimum of data structured?
    Conversely is the data all structured but the narrative just auto-generated with lots of redundant filler information like 'patient received <<DRUG>> for unknown indication'

Challenges related to improving data quality

EMA does not have the ability to change (non-master) cases in EV

The sender is the owner of the case & is the only one who can nullify or change it

Ergo, EMA must request senders to make changes, which can lead to such concerns as

- Conflicting demands
  - A case may be valid in one jurisdiction but not another. Nullifying it in one region can harm audit trail
- Company policies
  - Internal SOPs/WINs may clash with EMA requests/requirements
- Fear of messing with data from regulators
  - Many MAHs want to align their databases as closely as possible to the data that NCAs hold
- MAH sold products & no longer has those cases in their database

Thank you

Further information

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