CBG MEB
MEDICINES EVALUATION BOARD

Opening remarks
Perspective: post-marketing, human

1 March 2024

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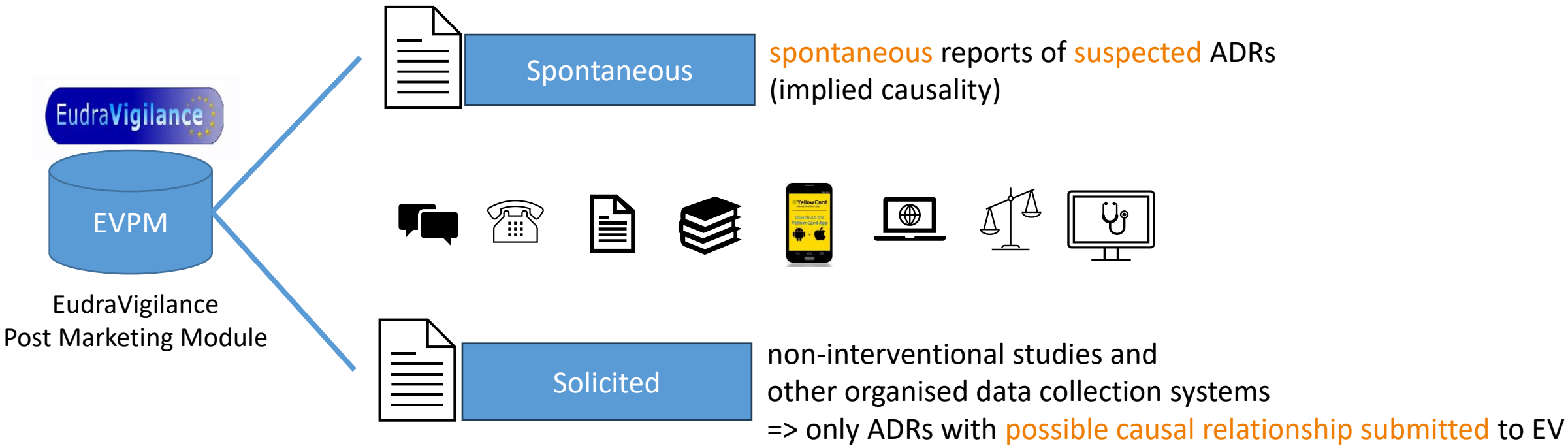
GOOD MEDICINES USED BETTER

1. Different ADR datasets within EVPM

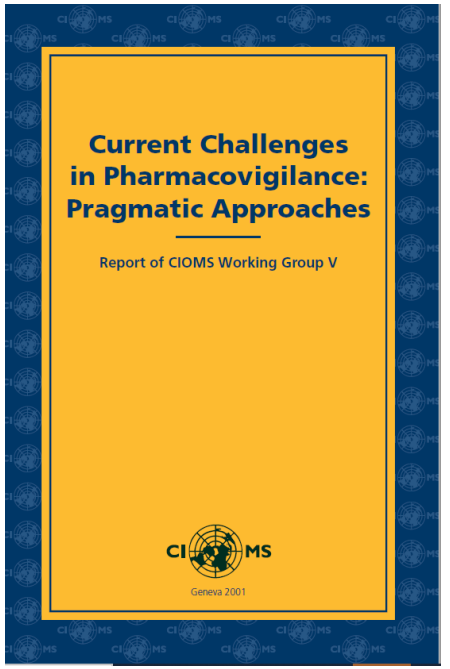


Fundamentally different data collection (passive vs active, mechanisms)
Different causality assessment requirement for submission to EV

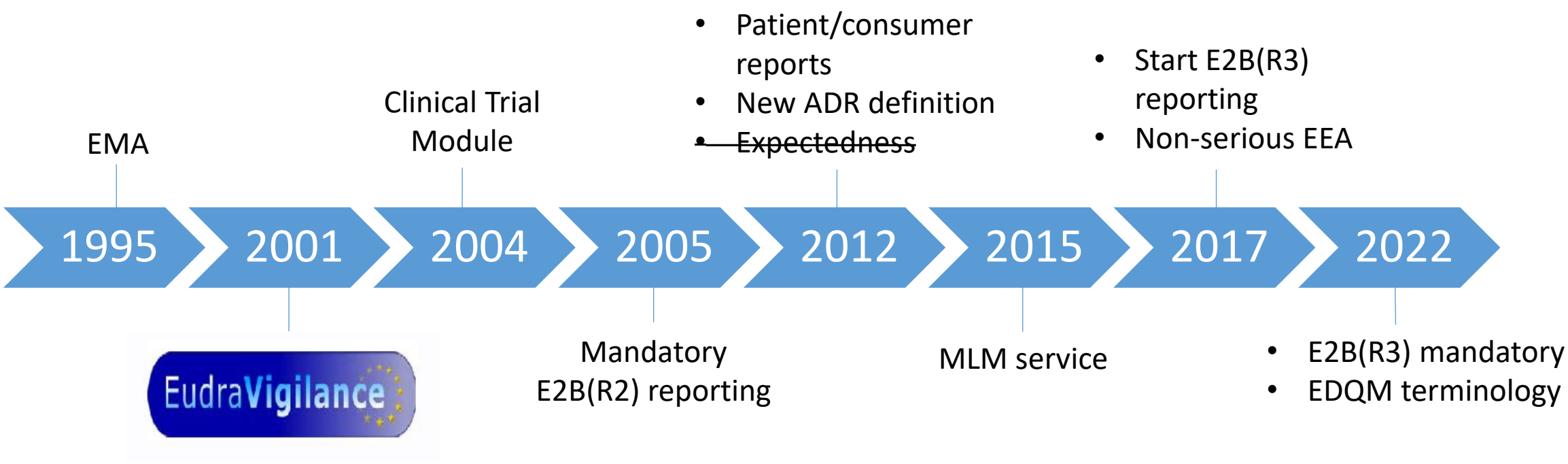
2. Aim of Spontaneous Reporting Systems (SRS)

Well known ~~limitations~~ characteristics of SRS include underreporting, reporting bias, no numerator/denominator data, risk of duplicates and variable quality of the reported data.

"The principle purpose of a spontaneous reporting system is to generate signals that may lead to the identification of previously unrecognized, suspected adverse drug reactions (ADRs), especially those that have serious outcomes. **These systems were not designed for, nor are they intended to be, complete collections of every adverse event that occurs to every person taking every drug.** " (CIOMS V, 2001)



3. Impact of EU legislation



EU legislation/guidance drives what is submitted by MAHs/NCAs, how it is submitted and the timelines

- be aware of impact of legislative changes on dataset, incl. quality aspects

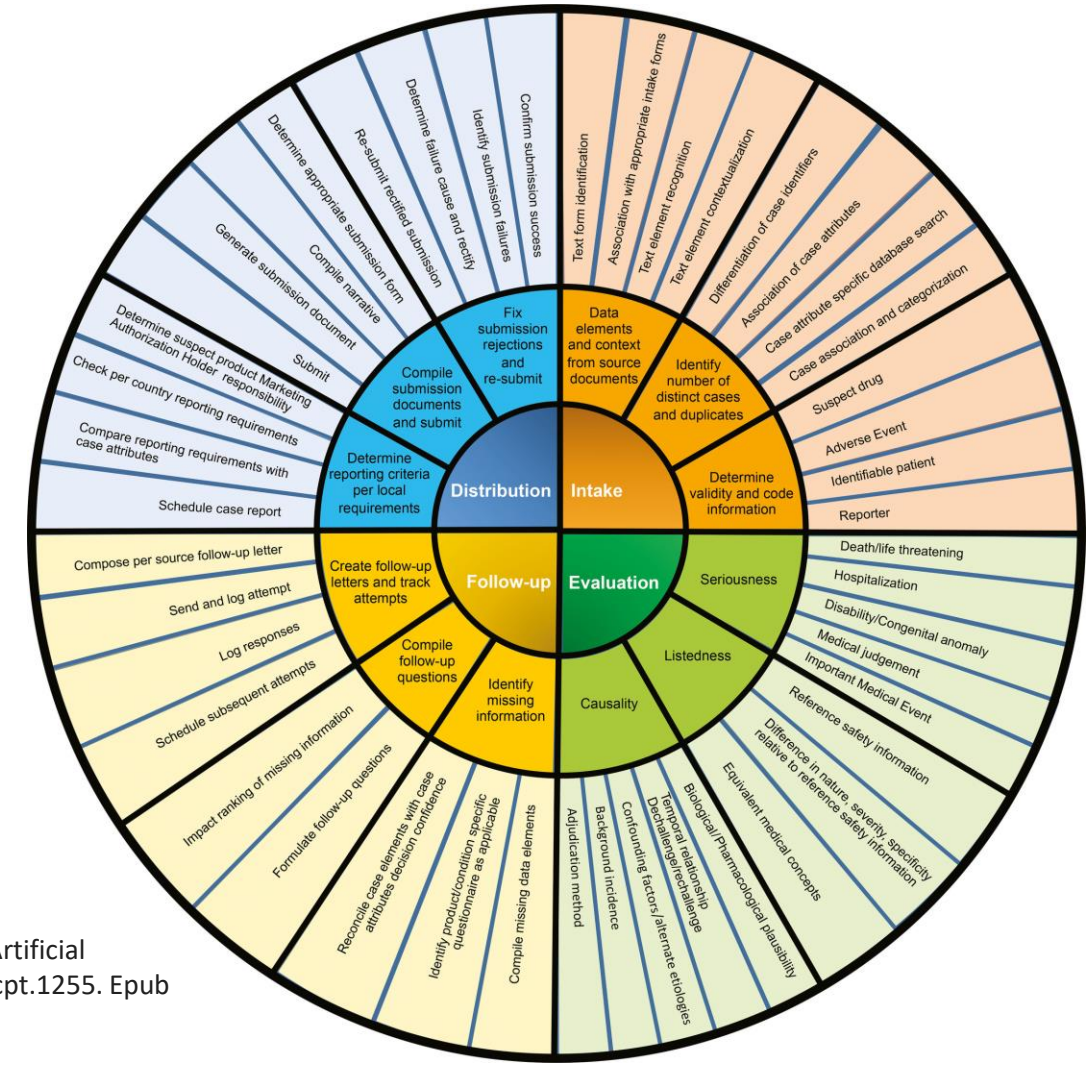
4. Quality controlled processes

Robust processes are in place:

- to collect valuable data from primary sources (incl follow-up)

- to ensure that database accurately reflects the source file, in line with GVP VI, ICH E2B(R3), MedDRA PtC

- to process ICSRs

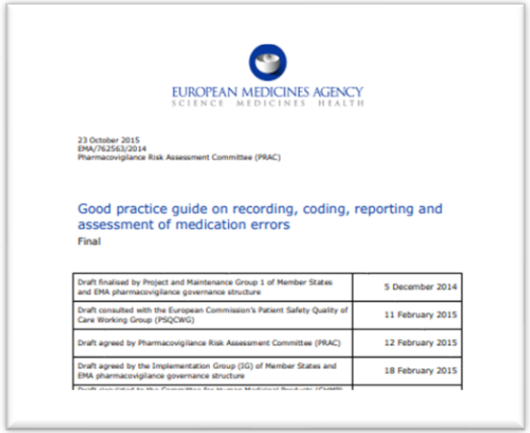


Schmider J, Kumar K, LaForest C, Swankoski B, Naim K, Caubel PM. Innovation in Pharmacovigilance: Use of Artificial Intelligence in Adverse Event Case Processing. Clin Pharmacol Ther. 2019 Apr;105(4):954-961. doi: 10.1002/cpt.1255. Epub 2018 Dec 11. PMID: 30303528; PMCID: PMC6590385.

5. What makes a case a good case?

- If the data show that the AE reported as myocardial infarction is a real myocardial infarction?
- If a causal relationship can be established?
- If most 256 ICH E2B(R3) data elements have been populated?
- If the case triggers further analysis?
- Or…?

Details needed may depend on context in which the ADR occurred. Such details often don't have a dedicated structured data element in the E2B(R3) message.



Good practice guide medication error recording coding reporting assessment (europa.eu)

Front. Drug. Saf. Regul. 3:1187888.
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Thank you for your attention