

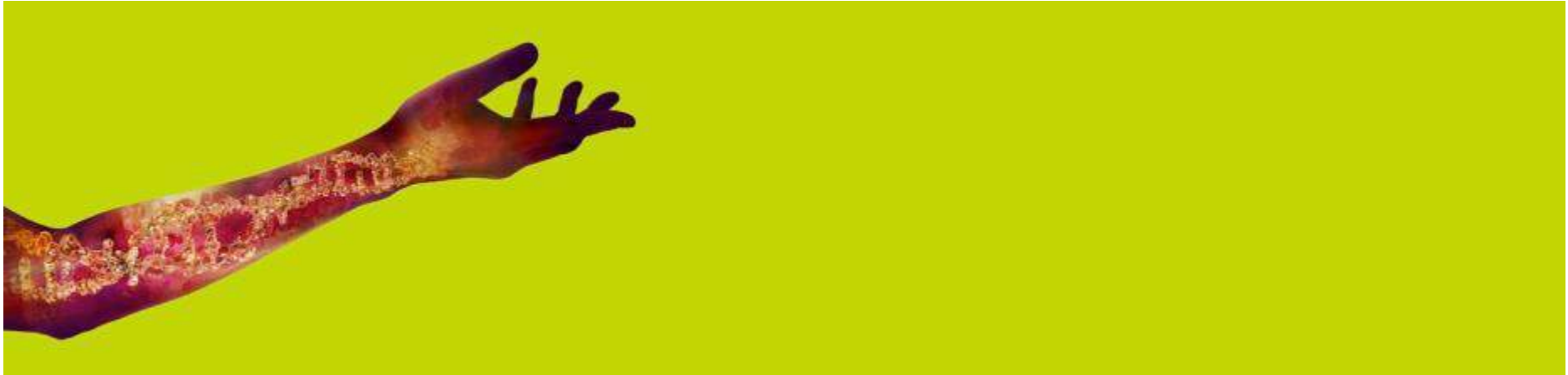
Digital Health Options for Post-Market Surveillance: Pharma perspective

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Round Table

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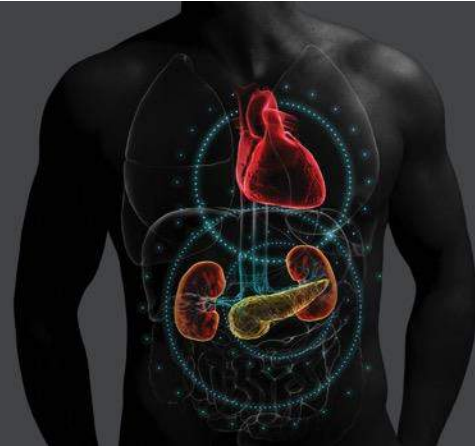


Group in three
broad themes

Incoming – collect data

Analysing – process, analyse and assess

Outgoing – provide information and advice



Vision

Collecting data

- Fully digital spontaneous Adverse Event reporting
- Social media listening to identify adverse drug effects early
- Broad use of patient-facing technology, eg wearables and internet-of-things for real-time monitoring
- Routine use of patient registries / RWE data sources for post-marketing surveillance (and conducting randomized late stage trials)
- Routine use of EHR data sources for post-marketing surveillance (and conducting randomized trials)



Collecting data



- Digital AE reporting
- Social media listening
- Patient-facing technology
- Patient registries / RWE
- EHRs as data sources

RECOMMENDATIONS ON THE USE OF SOCIAL MEDIA IN PHARMACOVIGILANCE, published Aug 24, 2019¹

- General social media, as exemplified by sample data from Facebook and Twitter, are not recommended for broad statistical signal detection.
- Social media channels may provide a useful adjunct to pharmacovigilance activities in specific niche areas such as exposure during pregnancy and abuse/misuse of medicines.
- Future enhancement of adverse event recognition algorithms may broaden the scope and utility of social media over time.

¹van Stekelenborg, J. et al. Drug Safety (2019). <https://doi.org/10.1007/s40264-019-00858-7>

Mobile application developed²

Allowing patients to directly report potential medicine side effects and also receive reliable information on their drugs

Learnings:

- App will only be used if it also provides useful information.
- Challenge: no common vocabulary
- Has been revolutionary to collect AEs in developing world

²Pierce, CE et al. Drug Safety (2019) 42: 477. <https://doi.org/10.1007/s40264-019-00813-6>



Address the barriers to the use of patient-facing technologies in clinical trials to benefit individual patients and the broader patient community, as well as sponsors, sites, and vendors.

- Social media listening
- Digital AE reporting
- **Patient-facing technology**
- Patient registries / RWE
- EHRs as data sources

Clinical trials can be transformed through patient-facing technologies by:

- Improving the patient experience in trials (e.g.: less site visits)
- Enabling broader participation in trials (e.g.: remote participation)
- Enabling collection of richer, more meaningful data (e.g.: real-world, real-time)
- Improving outcome measures to positively impact the broader patient community (e.g.: improved safety profiles)

Despite these benefits, there is limited use of patient-facing technologies within clinical trials:

- Lack of collaboration and knowledge sharing among various players in the clinical ecosystem (e.g.: sponsors, regulators, vendors, patients).
- General lack of regulatory certainty due to lack of regulatory guidance and a limited understanding of global regulatory perceptions

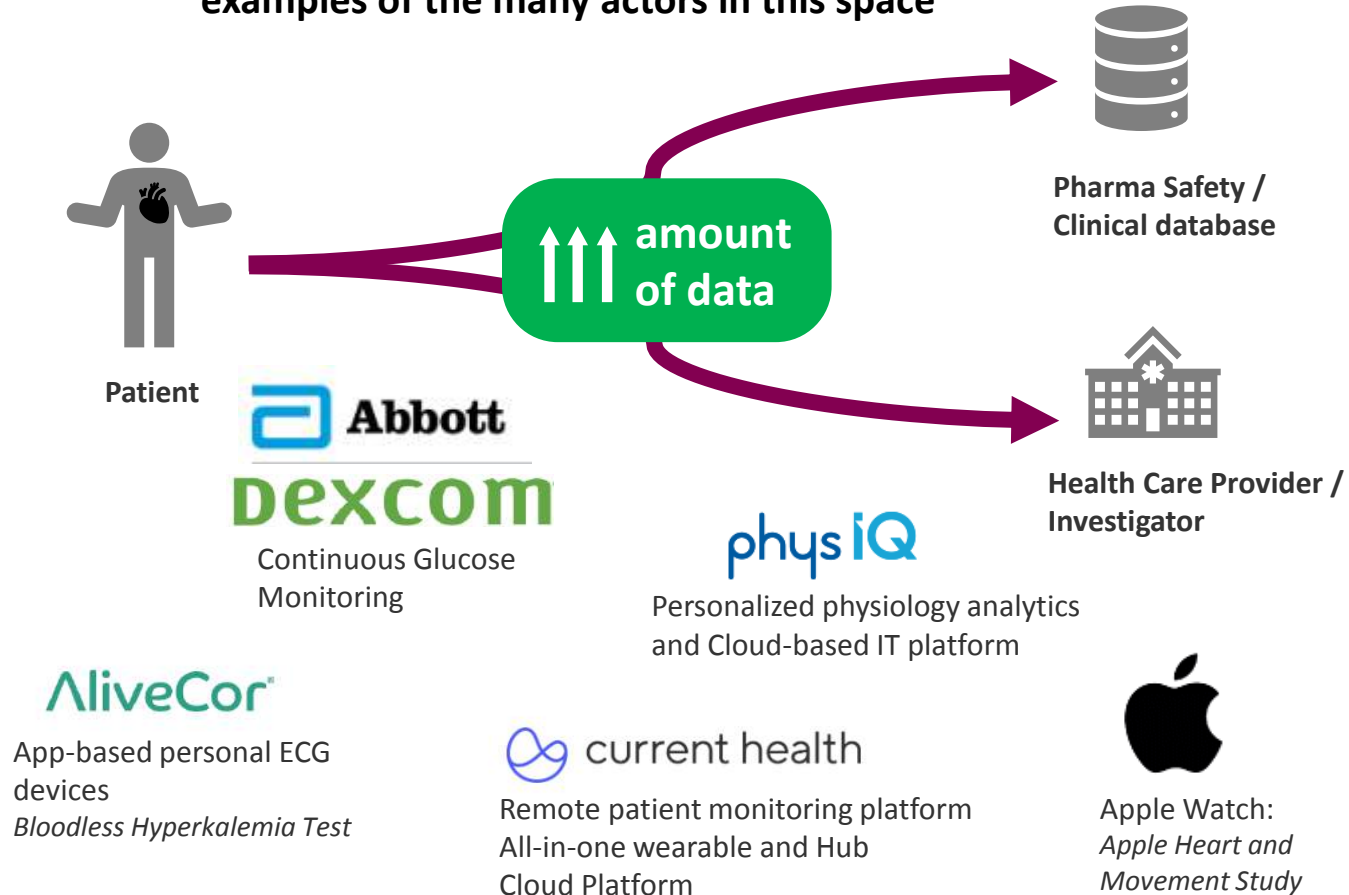
Greater collaboration and knowledge sharing among regulators, sponsors, vendors, patients and other players in the clinical ecosystem to address these barriers.



Collecting data

- Social media listening
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examples of the many actors in this space

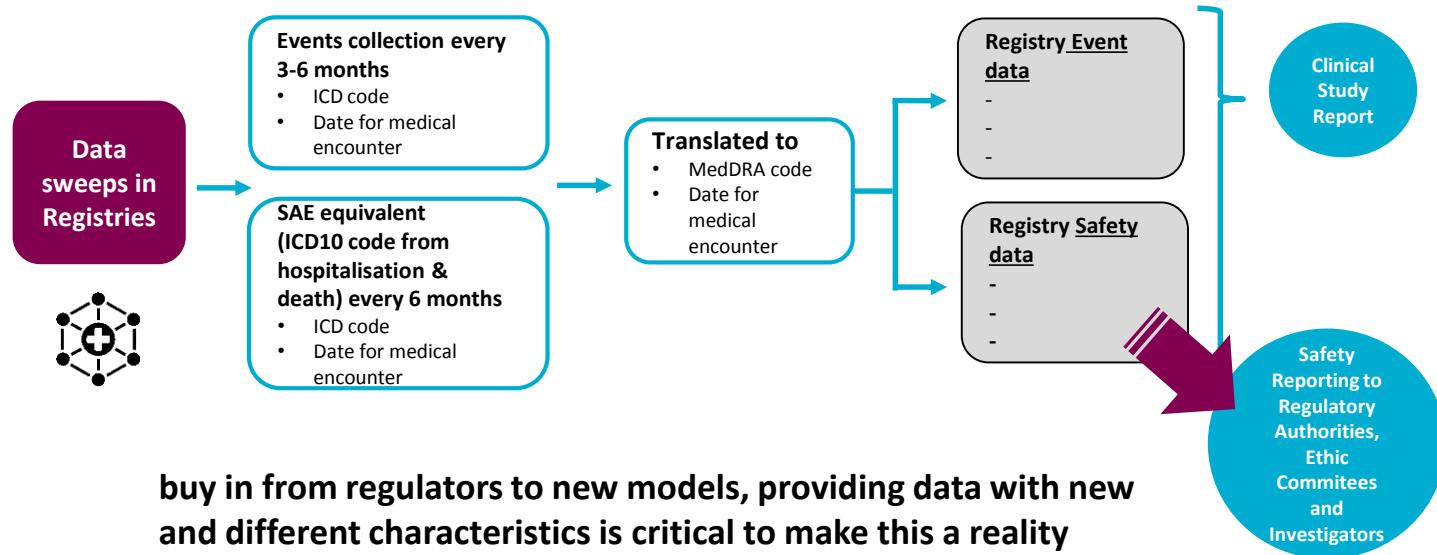


Collecting data

- Digital AE reporting
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Registry-based randomized clinical trials (R-RCT)

- prospective randomized trials that use a clinical registry for major functions for trial conduct and outcomes reporting
- run as an integrated part of normal clinical workflow (recruitment/enrollment, randomization and follow-up)
 - **essentially run the study in the registry** –
- leverage a nationwide network of outcome reporting that minimize study impact on regular care
- high quality registries is foundation



buy in from regulators to new models, providing data with new and different characteristics is critical to make this a reality

Collecting data



- Digital AE reporting
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- **EHRs as data sources**

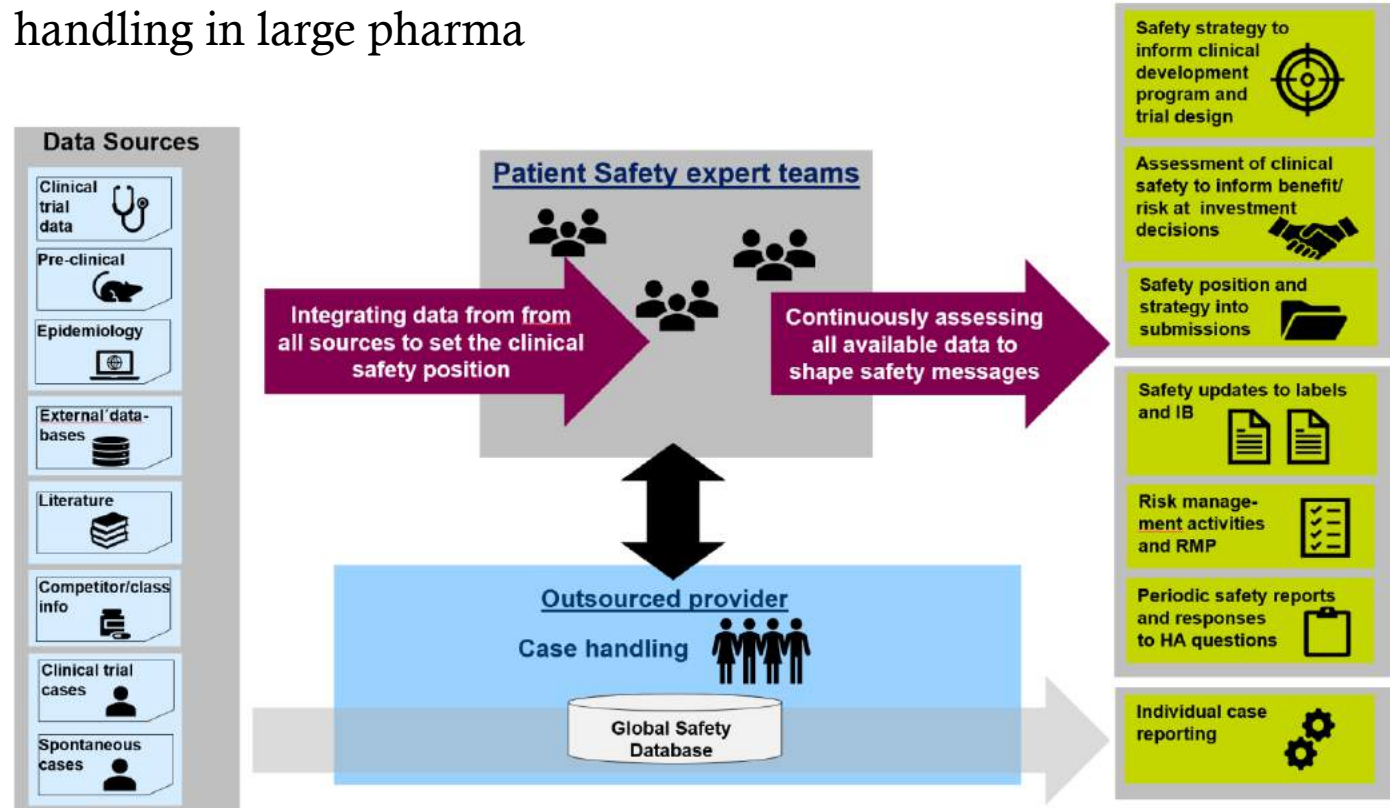
- Public-private consortium of pharma, hospitals, a platform technology provider and a not for profit institute.
- Partially funded by the EIT-Health Program of the European Commission.
- Build capability and a novel platform to enable a trial sponsor to pre-populate electronic data collection (EDC) system directly from electronic health records (EHRs), working across multiple EHR and EDC system vendors and products.



Vision

Process,
Analyse,
Assess

Overview of safety data and information handling in large pharma



Vision

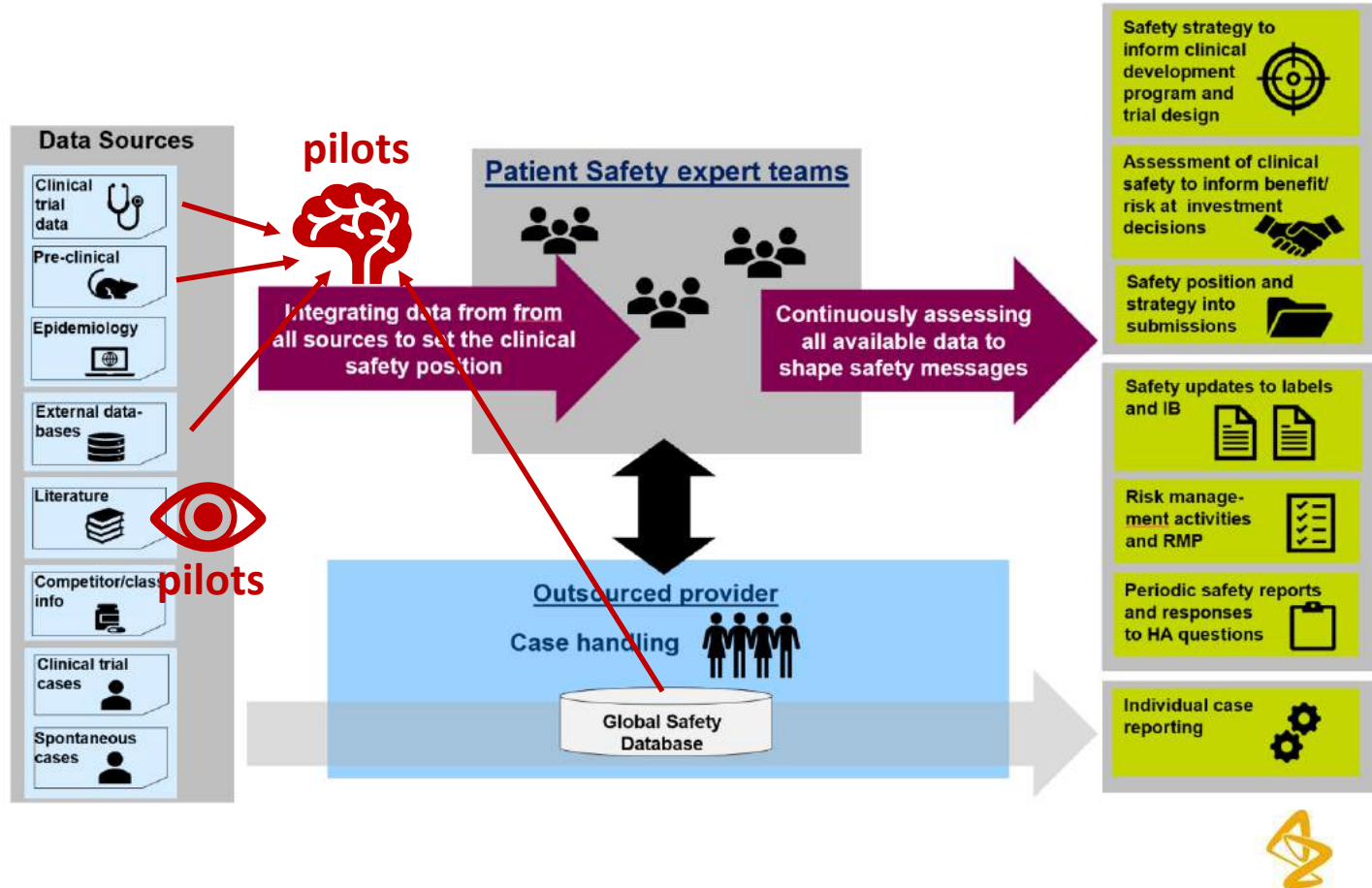
Process,
Analyse,
Assess

- NLP (Natural Language Processing) aiding literature monitoring (across languages and countries)
- Artificial Intelligence to detect signals in complex datasets
- RPA (Robotic Process Automation) and rules-based automation replacing manual tasks in case handling



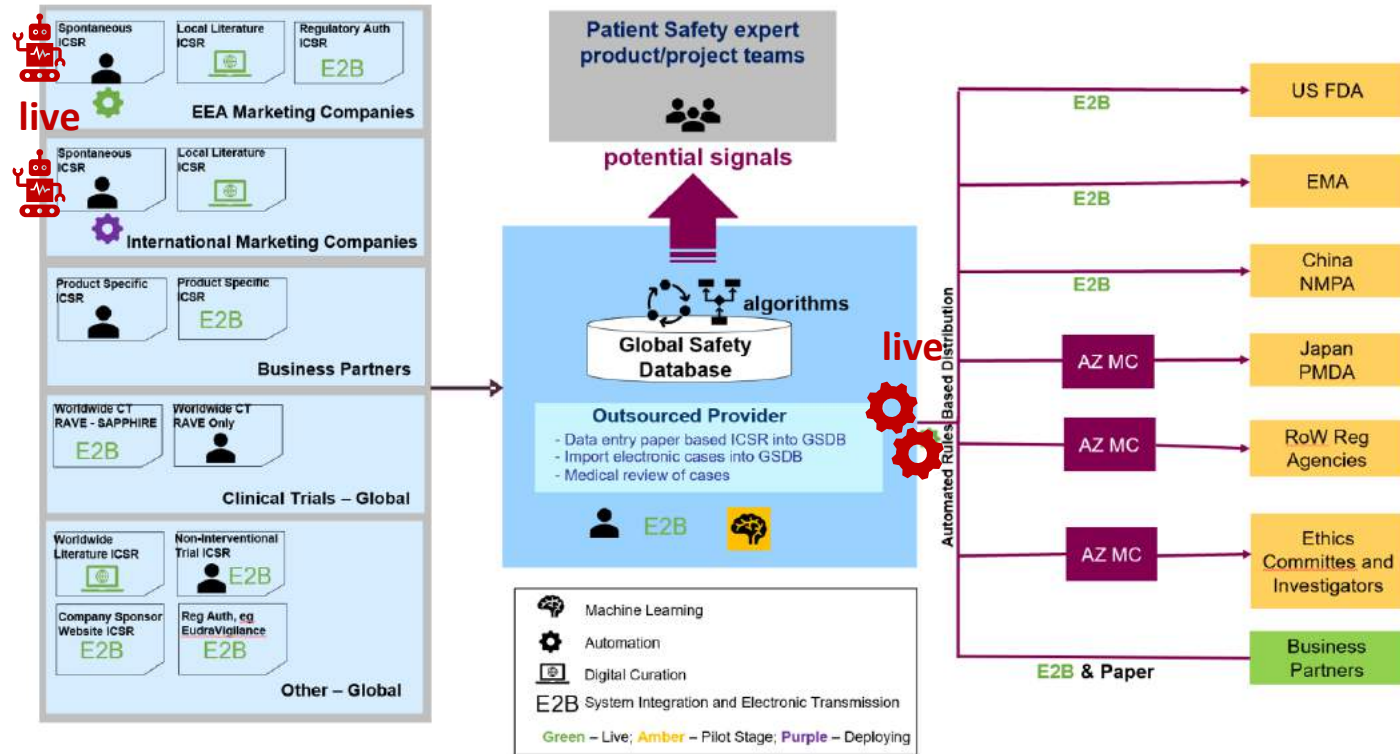
Process, Analyse, Assess

- NLP in literature monitoring
- AI in signal detection
- RPA and std automation in case handling



Process, Analyse, Assess

- NLP in literature monitoring
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Vision

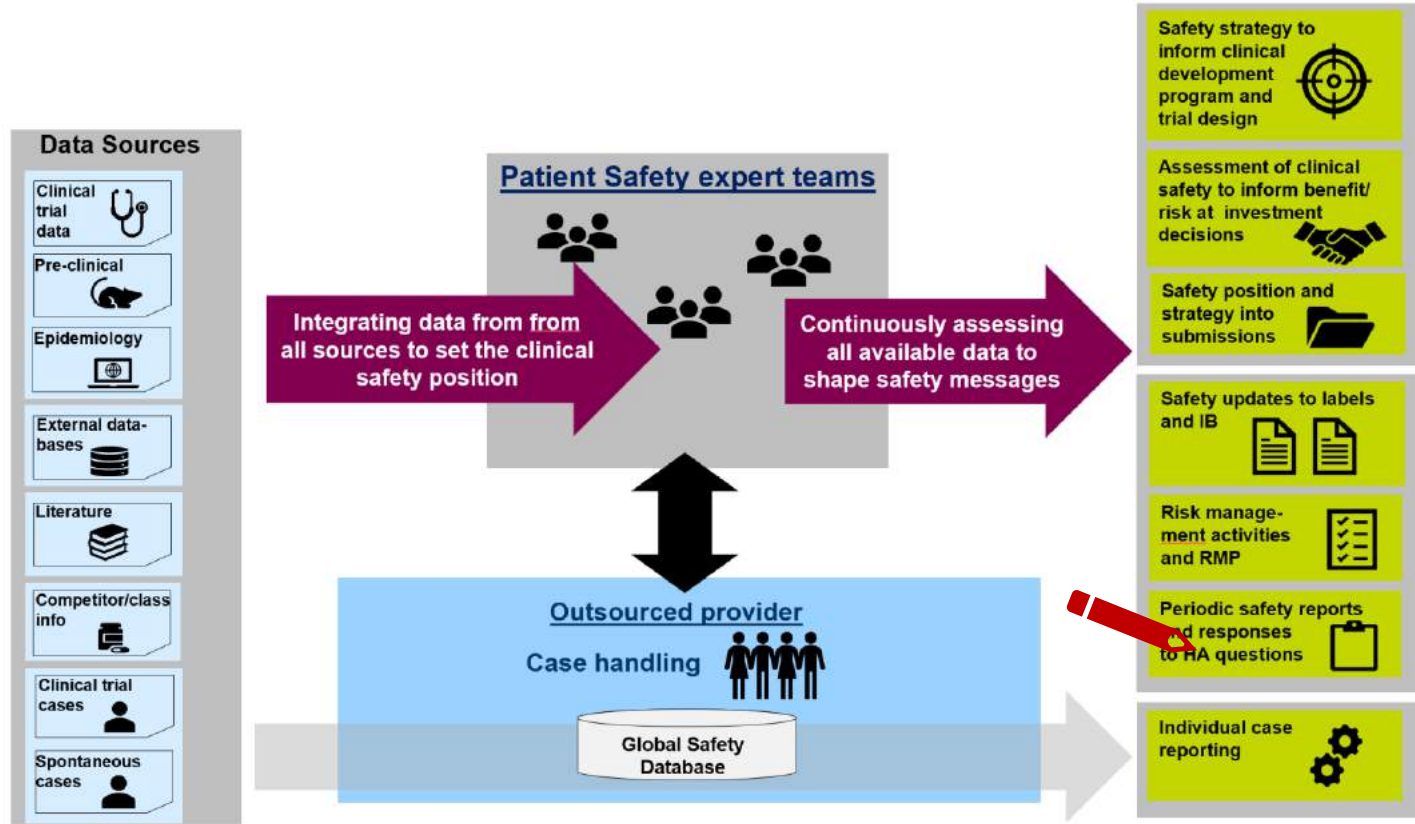
Provide
information
and advice

- Automation and NLG (Natural Language Generation) to produce standard reports to regulators, IRBs etc
- Augmentation of Risk minimization measures with artificial intelligence / machine learning
- Full utilization of digital channels for safety communication to HCPs and patients



Provide information and advice

- NLG for standard reports
- AI in Risk minimization
- Digital safety communication



Provide information and advice

- NLG for standard reports
- AI in Risk minimization
- **Digital safety communication**



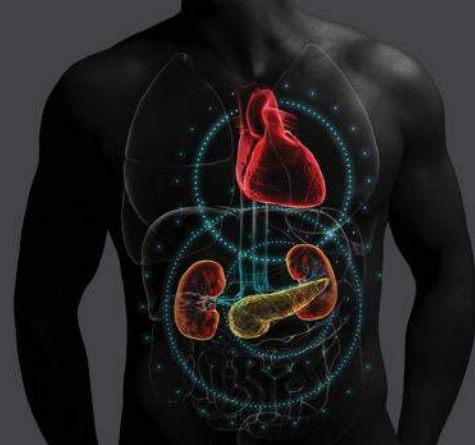
- User/patient friendly
- Track uptake

Educational materials targeting young patients with T1DM in 2019
Paper only for patients – not an option
HCPs – expecting digital in some countries



Concluding remarks

- many opportunities, need to **prioritize**
- increase patient, trial participant, HCP and investigator **satisfaction**
- increase **quality** and decrease costs
- technology is available – **we** have the datasets to train algorithms
- the more advanced technologies are mainly in **piloting**
- need to **work together**
 - pharma companies
 - clinical academic community
 - regulatory authorities
 - tech companies
 - data science community



Acknowledgements

Antoni Wisniewski

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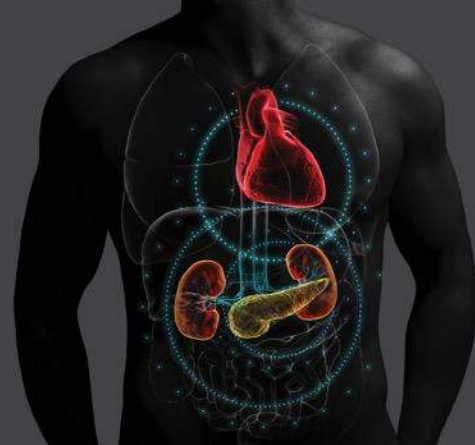
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Thank you

