

REPÚBLICA PORTUGUESA
SAÚDE

SISTEMA NACIONAL DE FARMACOVIGILÂNCIA
Notificação de Reações Adversas a Medicamentos
Profissionais de Saúde

Notifique sempre que suspeitar de uma reação adversa

A. Reação adversa a medicamento (RAM)

Descrição	Data início				

Considera a reação adversa (ou o caso, se mais do que uma reação)² grave? Sim ☐ Não ☐

Se sim, porque considera grave?

☐ Resultou em morte ☐ Resultou em incapacidade

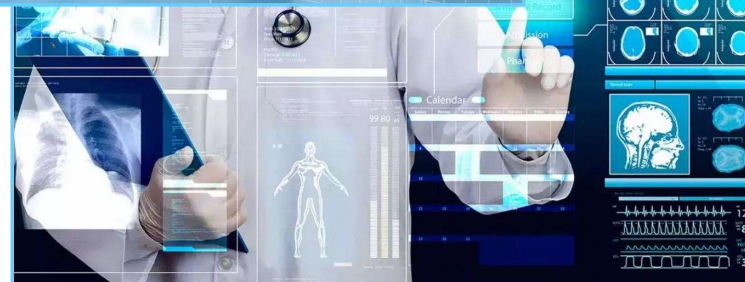
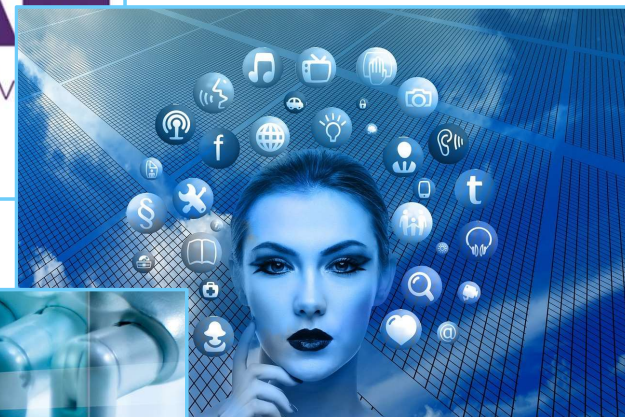
☐ Colocou a vida em risco ☐ Causou anomalias congénitas

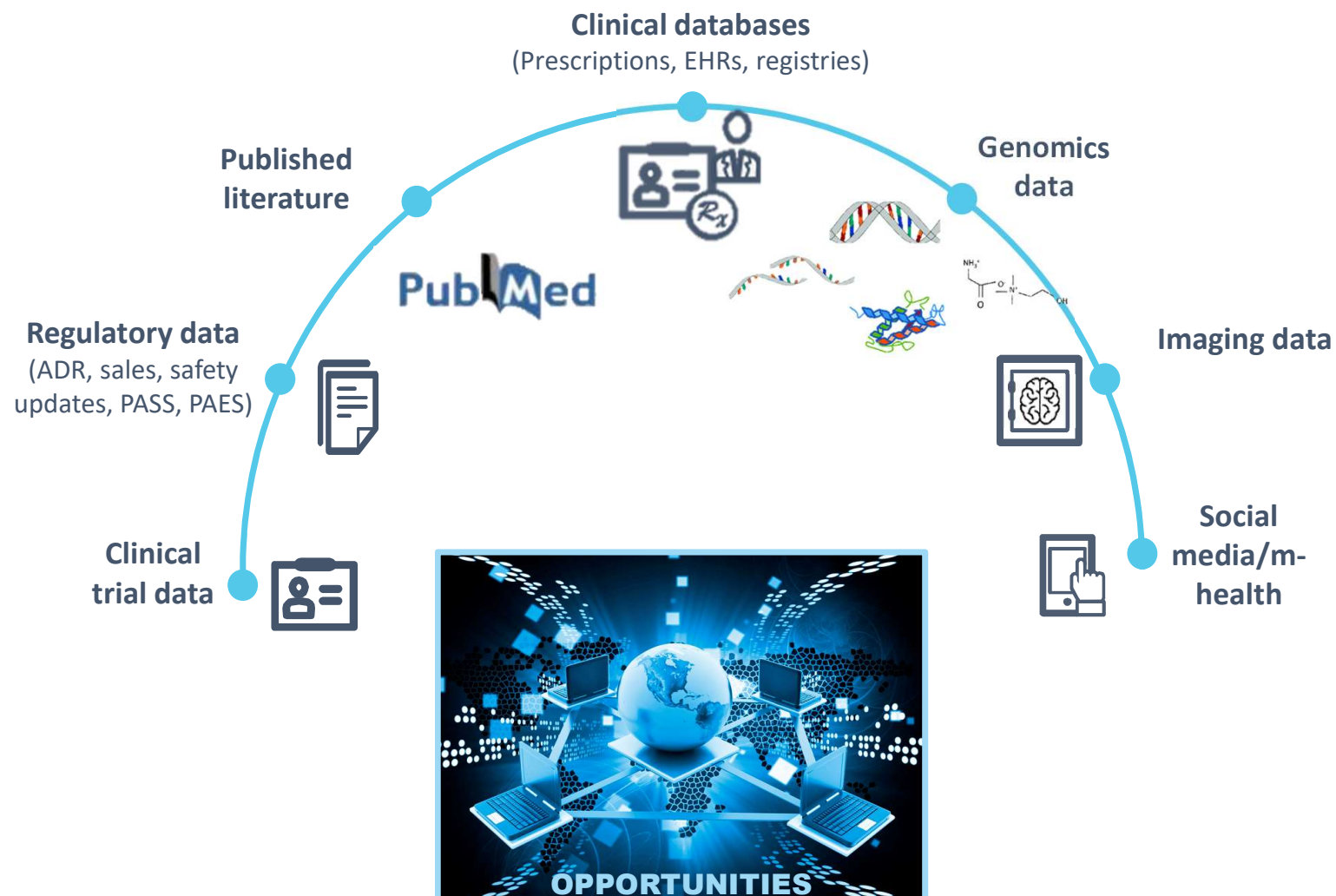
☐ Motivou ou prolongou internamento ☐ Outra³ (especifique e)

Tratamento da reação adversa:

B. Medicamento(s) suspeito(s)

Nome de marca	Lote	Dose diária	Via adm.	Indicação





PROBLEM

Advances in information technology are driving the digitisation of large volumes of research and clinical data (big data).

Standardised and pre-specified analysis of this data will require verification.

While these data offer possibilities for gaining new insights, the acceptability of these insights as a source of evidence for regulatory decision-making, is uncertain.

We currently have limited capacity to access and analyse large sets of heterogeneous and unstructured data.

We are not yet ready to guide the use of emerging technologies in critically interpreting big data-based analysis or new analytical approaches.



VISION

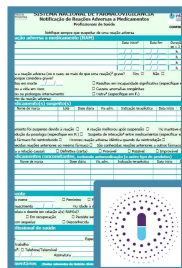
Strengthening the regulatory system through the efficient integration of big data analysis into its assessments with a view to improving decision-making.

Knowledge of data sources, their quality and relevance to the population, and optimising the culture of data sharing.

Knowing when and how to have confidence in new technologies and evidence generated from big data will benefit public health by accelerating drug development, improving treatment outcomes and facilitating early access to new treatments.



ARE WE ALREADY THERE?



Smarter collection of ICSRs



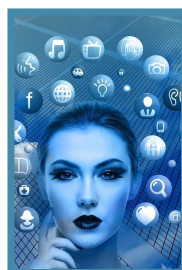
**Improve patients and
healthcare professionals
engagement**



Use of mobile health tools



Disease Registries



Social media screening



Digitalisation of healthcare

We expect to see more efforts to holistically integrate **artificial intelligence** across the pharmacovigilance lifecycle as the need for rapid and effective learning from emerging data for decision-making became even more evident during the COVID-19 pandemic



Artificial intelligence systems can achieve their maximum impact on data entry and processing, making overall surveillance activities more effective, including for security





OBRIGADO

