Novartis International AG
Data Privacy

Fine tuning in light of the new GDPR

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The use of personal data will improve therapies

Illustrative example

Patient John

Physician visit

Physician diagnoses cancer and prescribes oral cancer drug; informs John about **Beyond the Pill** solution

Diagnosis and prescription

Pharmacy

John picks up drug from pharmacy, **bar code** on package to download app

Pick up

home setting

John scans barcode to download app, gets **on-boarding call** from telenurse; John puts on **sensor patch**

Log-on

Sensor monitors **pill intake** and biomarkers indicating **gastrointestinal infection**, patch measures **temperature**, John answers standard **Patient Reported Outcomes** on side effects daily; app sends John **advice** on best nutrition and medication **reminders**

Home monitoring and Patient Reported Outcomes

Sensor detects early signs of **gastrointestinal** infection, **alert** sent to **John** with immediate countermeasures, alert sent to **physician**, physician contacts John and prescribes medication to **manage side effects**

Alert

Physician intervention

Continued treatment

John is **back on stable treatment**

Solution Elements

Adherence/ side effect App

Sensor 2.0

Artificial Intelligence algorithm

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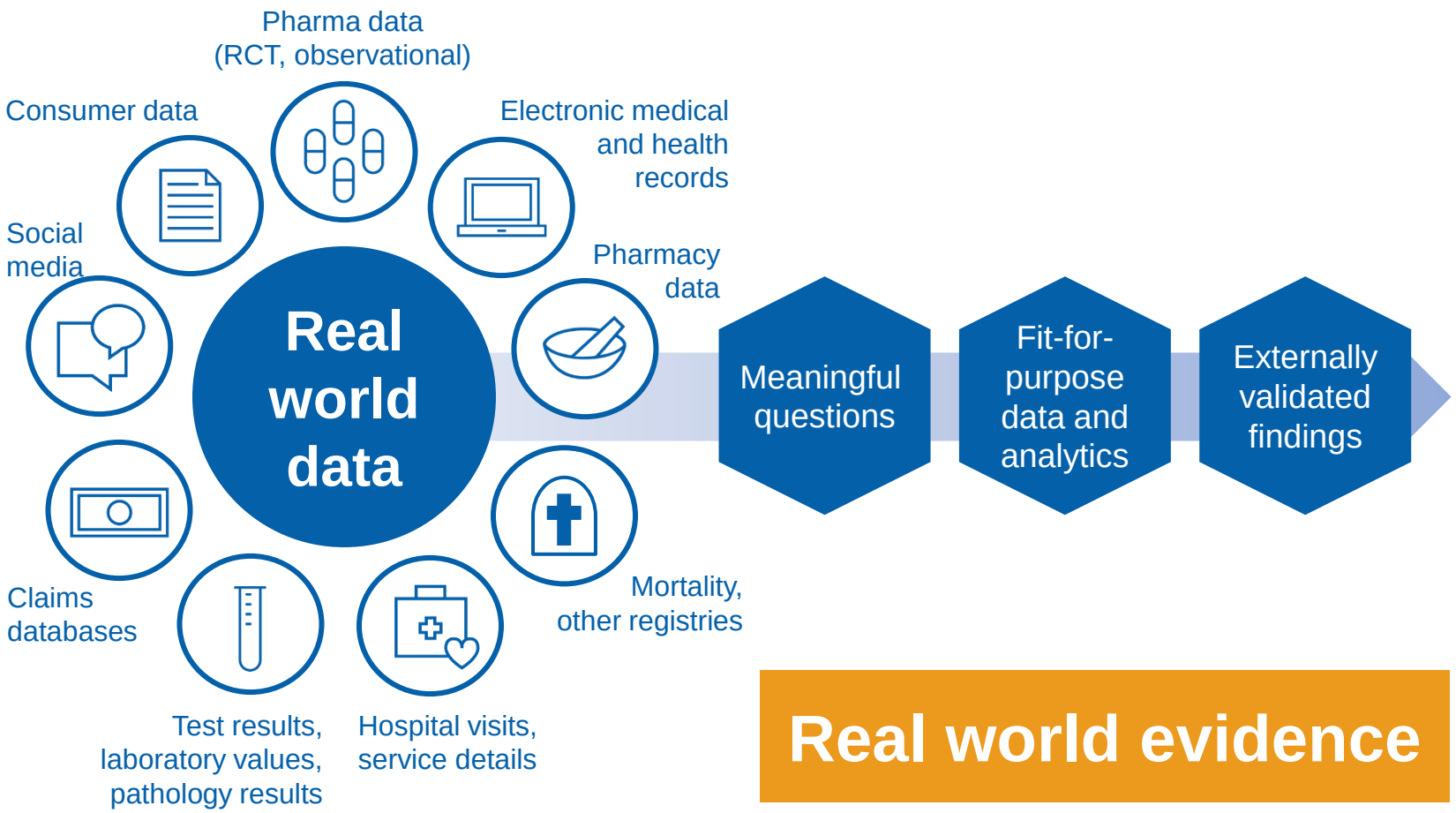
A new era for Personal Information



Real world evidence

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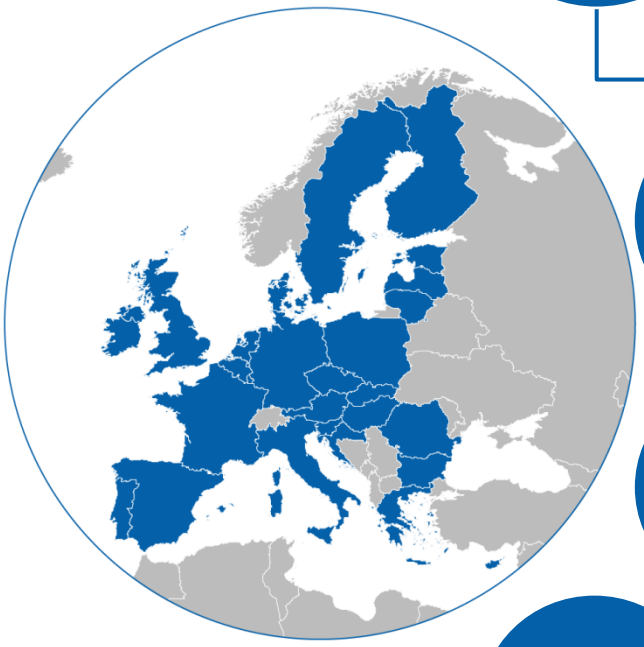
General Data Protection Regulation



Aim

- **To strengthen and unify data protection** in the EU (Regulation vs. Directive)
- More harmonization (still room for improvement)
- To address **export of data** outside the EU
- Better coordination among regulators

Scope

- Directly applicable in all EU Member States
- Applies to **goods or services** for EU citizens
- **Monitors behavior**
- Uses equipment **situated in the EU**

Timing

- Comes into effect **25 May 2018**
- GDPR is **evolving**
- May be **subject to variations** in individual EU state laws

Fines

- Breaches may lead to **administrative fines** of up to **4% of total group annual turnover or €20 million**

GDPR, General Data Protection Regulation

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Personal information – asset, risk and risk management

Privacy risk needs to be managed in the same way as other risks and assets

- Financial,
- Business practices (ABC, anti-trust),
- Health, Safety, Environment
- Quality.

Risk Management

- Assess business processes for privacy risks
- Implement adequate controls over privacy risks
- Establish clear accountability of 1st line (Business) and 2nd line (Data Privacy)

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Accountability - risk assessement and controls

Privacy by design and by default of projects and systems (art. 25)

Documentation of processing operations (art. 30)

Security of processing (art. 32)

Reporting of data breaches (art. 33-34)

Privacy Impact Assessments (PIA) for systems/processes (art. 35)

Data privacy officer designations (art. 37)

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