

# STAMP 9<sup>th</sup> meeting 8 June 2018

### Activities related to real world data





### **Presentation layout**

#### Introduction

- Definitions
- EC Communication on Digital health and care

EMA/ HMA intervention on regulatory framework

- RWD focused activities
- HMA/ EMA joint big data taskforce

Research projects H2020 and IMI EMA patients/ disease registries cases Discussion



### Introduction

- Definitions
- Commission Communication on digital health and care



### **Defintions**

- ✓ Big data = umbrella term describing large data sets from any source
- ✓ Real-world data (RWD)= any type of health-related data not collected in randomised controlled trials but derived from a diverse population in real life settings
- ✓ Diversity of sources
  - Registries & other types of observational studies
  - Extension of clinical trial
  - Medical health records
  - Health insurance databases/ Hospital databases
  - Data generated from mobile applications
- ✓ Collected by many different actors in the healthcare system.
  - \* Manufacturers, learned societies, patients' organisations, hospitals, healthcare professionals in routine practice, etc.



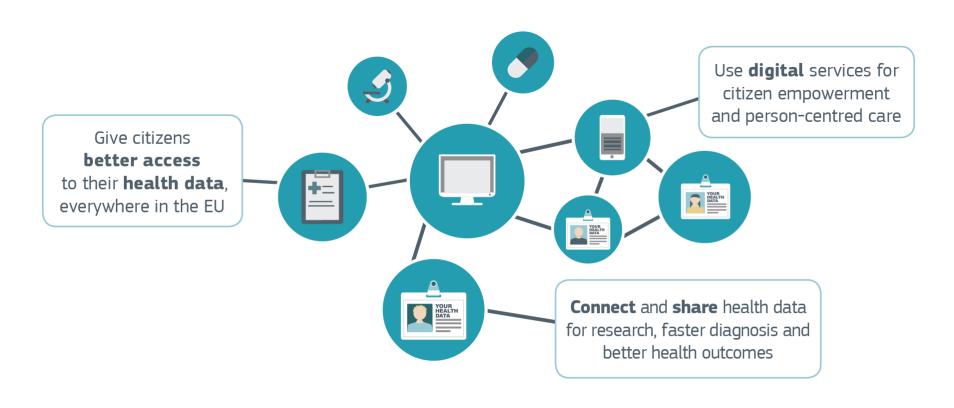
# Communication on the digital transformation of health & care (DIGICARE)

- ✓ Adopted on 25 April 2018
- ✓ Objective: to increase the availability of data in the EU to improve healthcare, and clinical research
- ✓ Links to the Communication

Communication: <a href="https://ec.europa.eu/digital-single-market/news-redirect/624248">https://ec.europa.eu/digital-single-market/news-redirect/624248</a>
Staff working document: <a href="https://ec.europa.eu/digital-single-market-market/en/news/staff-working-document-enabling-digital-transformation-health-and-care-digital-single-market">https://ec.europa.eu/digital-single-market/news-redirect/624248</a>
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# Communication on the Digital Transformation of Health & Care – 3 pillars





# EC Communication on the digital transformation of health & care (DIGICARE)

- ✓ Under Pillar 2: Pilots to demonstrate the benefit of the use of RWD for HTA, clinical decision making and regulatory decision-making
  - Should address the needs of different target groups (healthcare professionals, regulators, health technology assessment bodies, policy-makers)
  - ❖ Building on ongoing data collection efforts within societies of clinicians
  - Synthesis of results derived from completed, on-going, planned & future EU-funded initiatives (e.g. H2020 projects, IMI projects, Joint actions) to derive guidance documents