



STAMP 9th 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: <https://ec.europa.eu/digital-single-market/news-redirect/624248>
Staff working document: <https://ec.europa.eu/digital-single-market/en/news/staff-working-document-enabling-digital-transformation-health-and-care-digital-single-market>

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