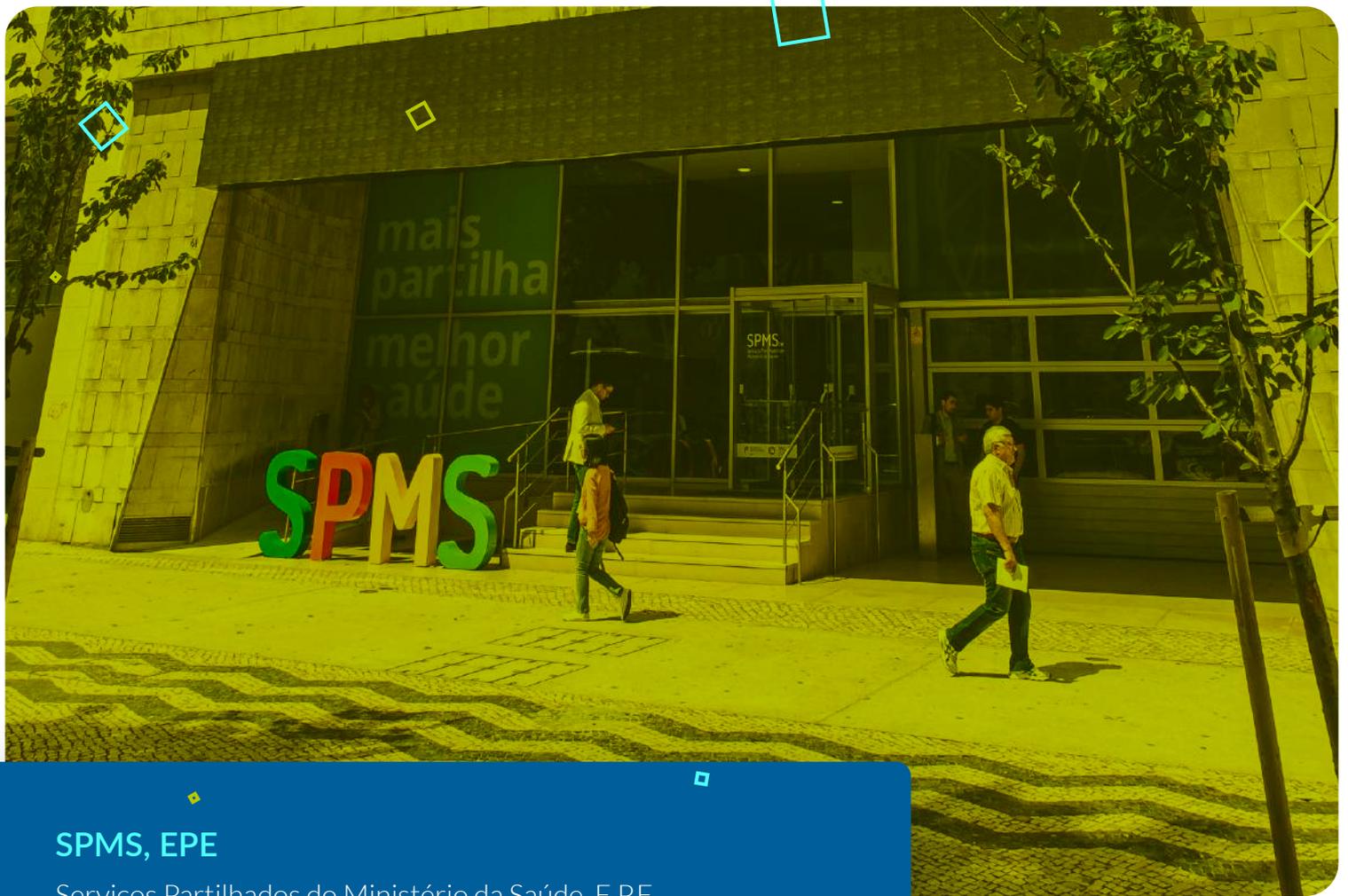


Towards the European Health Data Space

National Strategies for Secondary Use of Data in the Context of National and EU Digital Health Networks

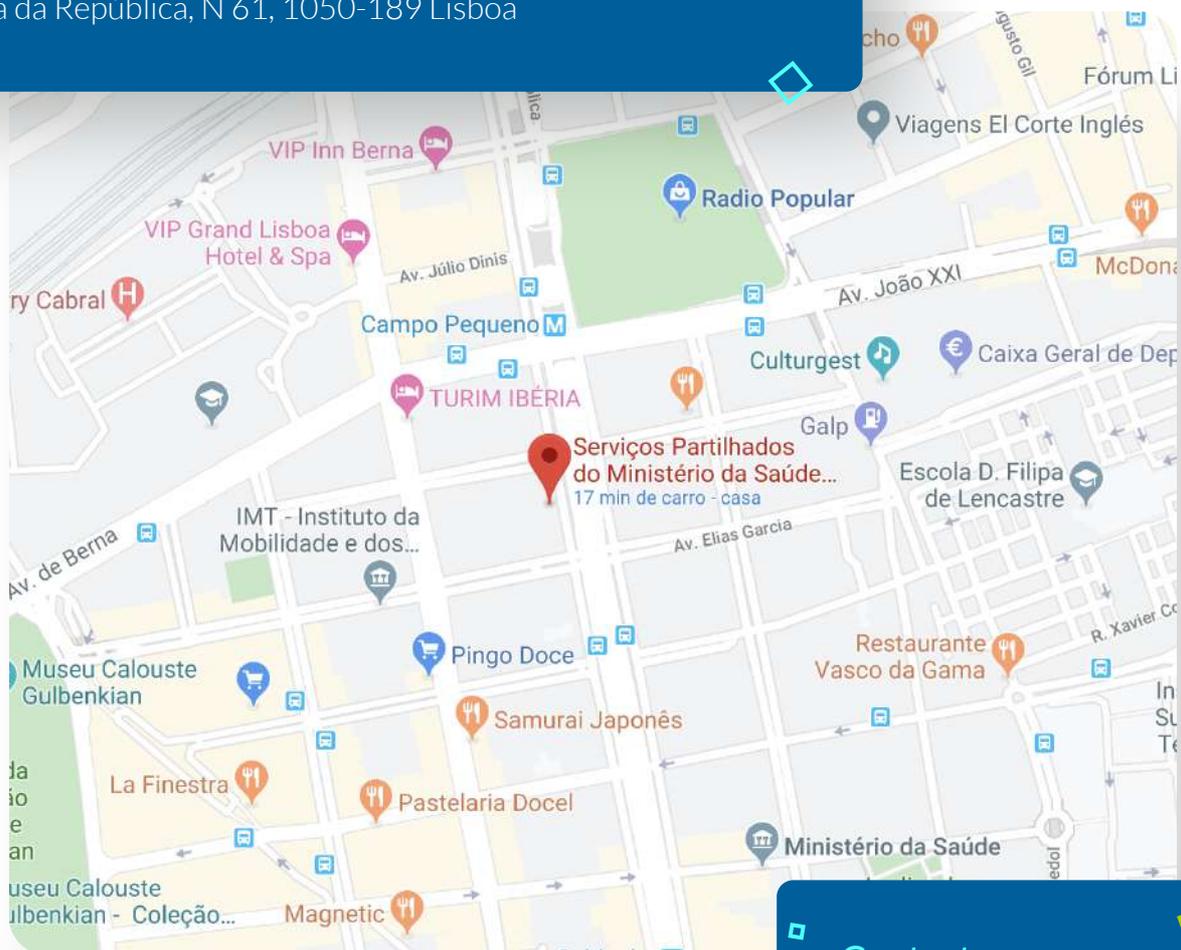
Workshop on Health Data Governance for Secondary Use

21-22
JANUARY
2020



SPMS, EPE

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SCOPE AND OBJECTIVES

The eHealth Network has set up recommendations for governance models and cross-border actions for development of National Digital Health Networks (NDHNs) as a critical step towards interoperability and secure exchange of health data across borders (among other important related purposes). These recommendations intend to consolidate a national structure that can be aligned with the Joint Coordination Process as well as support national digital health strategies.

Secondary use of data has become one of the major cornerstones of digital transformation for health systems improvement. Realizing the promise of eHealth, the "safe use of information to support health and health related factors" will require robust governance and leadership at national and international levels, multisectoral collaborations to establish the technical-scientific base and definition of shared models to improve quality, while ensuring respect for the principles of data protection, privacy and fairness. Data science and artificial intelligence, supported by high-quality data are expected to improve quality of care, management of resources and sustainability generating data-driven insights and innovation.

The upcoming debate on the Health Data Space, which creation is stated in the mission letter to the new European Commissioner for Health reinforces the need to strengthen international cooperation for a shared policy agenda around data governance. As a preliminary/working definition one can conceive of a Health Data Space, both at National and at European level, as an ***“aggregate of systems and data that are relevant for health policy, planning, research and patient care, that can be used by information systems in a holistic manner for any secondary use of health data purposes”***.

SCOPE AND OBJECTIVES

This two-day workshop will tackle national data governance models and national strategies for secondary use of data. It is intended to address policy, technical and legal/regulatory frameworks for data collection and sharing for secondary use purposes, sources of health-related data and national initiatives on secondary use of data, either for personalized medicine and public health.

The main goals to achieve at the end of the work plan are:

- Define the European and National “Health Data Space” both in theoretical and operational perspectives;
- Identify priority domains and areas of work at the EU level for a “Health Data Space” at policy and operational levels;
- Map national data governance models and policies regarding secondary use of data in EU Member states;
- Define the role of National Digital Health Networks in health data governance and secondary use of data;
- Map national initiatives on secondary use of data for health planning, personalized medicine and public health;
- Identify joint efforts between Governments, Healthcare Organizations and National Agencies for secondary use of data at the EU level;
- Share information, best practices and expertise (re-use of the existing resources);
- Create a network of national contact points with national responsibilities in health data governance and/or secondary use of data.

WORKSHOP METHODOLOGY

The workshop will adopt a **interactive format of work** to identify priority domains that need to be addressed in the **near future at national and European levels**, share best practices across different member states, raise awareness and foster capacity building that emerges from shared expertise.

It is also intended to increase the level of cooperation of EU Member states in the domains of data governance and secondary use, and to promote joint efforts between Governments, Healthcare Organizations and National agencies for eHealth.

WHO SHOULD ATTEND?

We expect **experts** with national leadership roles in health data governance bodies (or equivalent) and/or extensive experience in the field of secondary use of data either from a policy or operational level that deal with administration, IT, legal or data analytics domains of secondary use of data at national level.

It is intended for **1-2 national experts** (CISO & CSO) per MS:

- For eHealthAction member states participation costs can be covered by the eHAction plan. Other member states or individual agencies must cover costs, on their own voluntary basis.
- MS are requested to **engage a their most appropriate experts** and if necessary, consider supporting them to attend the workshop.

LINE - UP

DRAFT AGENDA

Tuesday January 21st, 2020

10h00

Registration & Arrival

10h30

Welcome & Introduction

Round of Table

10h50

Official Openings

Jamila Madeira, Secretary of state in the Ministry of Health (TBC)

Henrique Martins, Chair of Administration Board SPMS

Introduction to the workshop – expected outcome - Henrique Martins, SPMS

11h30

National challenges and opportunities in health data spaces (governance and architectures for secondary use of health data):

Presentation by each country about their national context 2/3 of presentation regarding **National Health Data Governance**

Possible questions to address in the session and others:

- Does your country have a health data strategy?
- Does your country have national/regional health data governance structures?
- Does your country have infrastructures for primary and secondary use of health data? If so, have you collaborated with the EU organisations and infrastructures (EMBL, Elixir, BBMRI, ECRIN, etc.) to build and operate these? What was your model of collaboration? If so, have you collaborated with industry to build and operate these? What was your model of collaboration?
- How have you tackled the legal, ethical, societal and operational challenges linked to a health data space in your country/organization?
- Indicate major national/regional initiatives to improve secondary use of health data of which your organization has been part of
- Policy and regulation
- Technology enablers & e-Skill for Professionals and Citizens towards the generation of quality health data

1/3 of presentation regarding EU Health Data Governance:

- What are the priority challenges at EU level?
- What kind of governance at EU level to allow MS to access data between MS?
- What are concrete infrastructure needs at EU level to allow MS to access data between MS? What model of sharing could work?
- Areas/Initiatives to cooperate at European level, including identifying priority areas where cooperation towards a EHDS can bring immediate gains (“low hanging fruit”).
- Are there building blocks and good practices that could help us move ahead?
- Describe your national and international partnerships for exchanging of health data for health systems improvement.

13h00

LUNCH

5

LINE - UP

DRAFT AGENDA

Tuesday January 21st, 2020

14h00

National and EU Challenges and Good Practices in national health data governance and secondary use of data:

Presentation by each country about their national context (CONT.)

eHActon WP.5 presentation

15h00

Overview of Topics covered in previous sessions

Objectives to be achieved by each of the working groups

Brainstorming – building together, priorities, capacity building for an EU Health data space

15h20

How we will work together at EU level?

Parallel Break-out Sessions

Main areas of work, priority issues and needs to be included in the final report;

Possible points to address in the session:

Two levels: National | European Union

National challenges and opportunities

- Identify barriers, challenges and opportunities
- List ongoing efforts and initiatives
- Short list main areas/initiatives to be included at National level
- Next steps, activities, responsibilities and timeline

EU common approach

- Brainstorm potential common work between MS and EU for the identified topic
- Short list main areas/initiatives to be included in the EU agenda
- Identify a framework for collaboration
- Next steps, activities, responsibilities and timeline

16h10

COFFEE BREAK

16h20

How we will work together at EU level? Parallel Break-out Sessions

(Cont.)

National challenges and opportunities

EU common approach

17h30

Preliminary break-out session report and Wrap-up of the day

19h30

DINNER

LINE - UP

DRAFT AGENDA

Wednesday January 22nd, 2020

09h00

2nd Day | Arrival

09h30

Wrap-up first day

09h40

Challenges and initiatives towards an European Health data space

- Current and future perspectives for a European Health data space
- Possible governance model for a European health data space
- Possible infrastructure for a European health data space
- EU legal and regulatory assessment for secondary use of data and data access across MS
- Technical and operational challenges of the EU Health data space

10h40

Research Infrastructures and Regulatory Agencies: vision and needs/possibilities toward a European Health data space

European initiatives presentation

11h40

Co-creating a EU Health Data Space exercise:

Survey results (tbc)

Presentation of survey's results

12h00

eHAction: implications for national strategies mapping Presentation

Workpackage 8

12h30

LUNCH

13h30

Future steps on Data governance and architectures models for European health data space, and implications for national digital health networks

- Future work under: eHAction, DG SANTE & EC
- Support the regulatory bodies
- Future Applications for DEP

LINE - UP

DRAFT AGENDA

Wednesday January 22nd, 2020

- From National to European;
- Governance, orchestration and definition of Health Data Spaces;
- How to apply data governance at EU level?
- How EU should organize to achieve Health Data Spaces: policy, infrastructures, centralize/descentralize;

15h50

COFFEE BREAK

16h00

Continue and discussion about the previous sessions

What are the top 5 priority areas in health data governance that benefit from networking, sharing of knowledge and eventually delivering guidance to inform national and EU strategies?

17h15

Closing Remarks

17h30

Adjournment

