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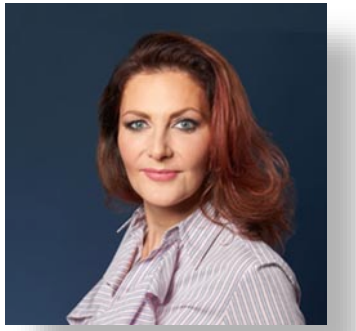
Improving healthcare decisions

Health Data, Health Data, and More Health Data: From Quantity to Quality Through Cooperation

ISPOR Warsaw 2019

28 March 2019

Health Data, Health Data, and More Health Data: From Quantity to Quality Through Cooperation



Katarzyna Kolasa
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European Commission

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Ministry of Health
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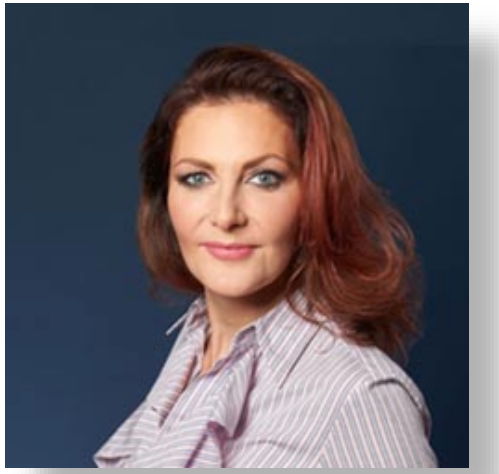

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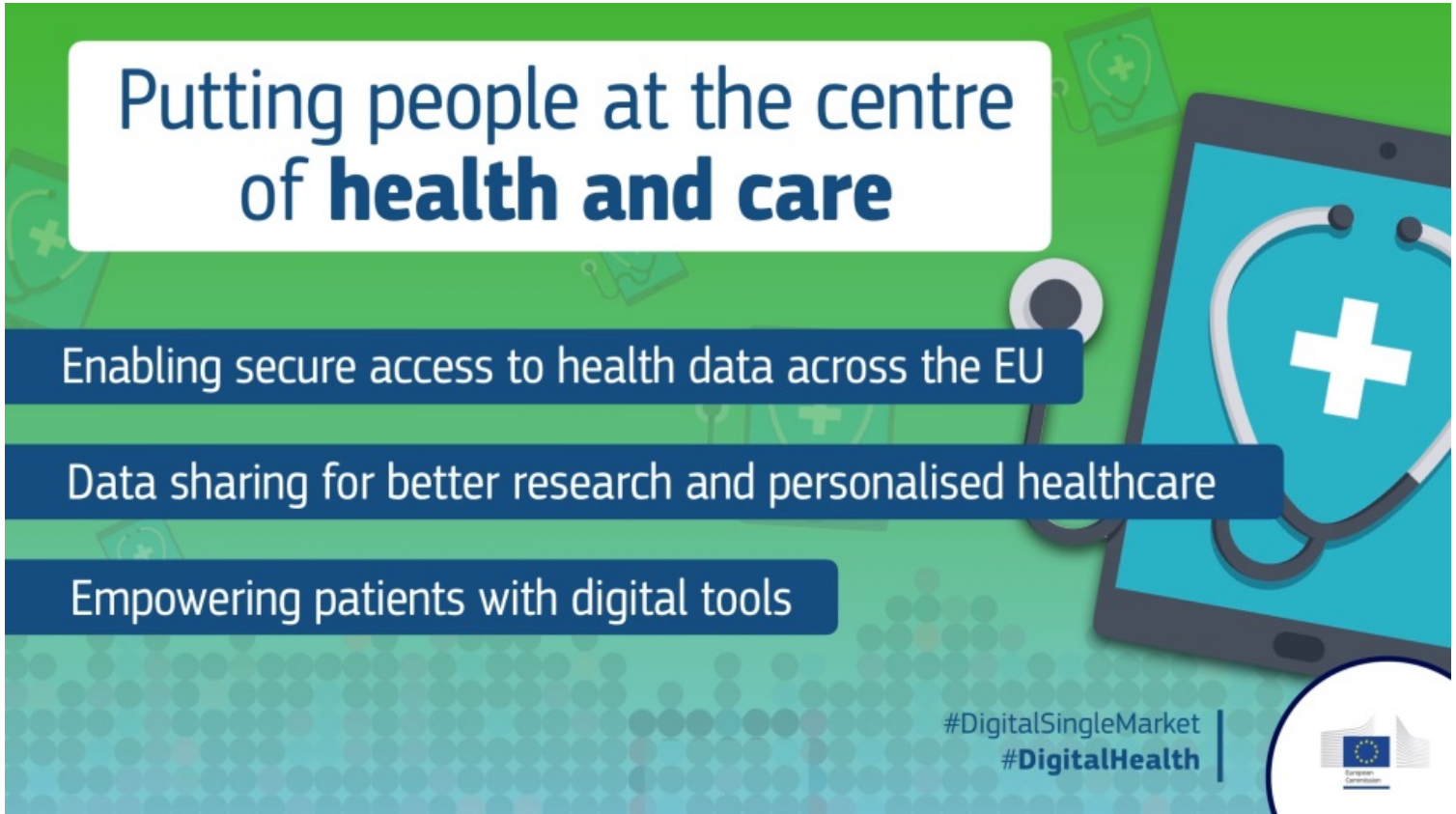
Health Data, Health Data, and More Health Data: From Quantity to Quality Through Cooperation

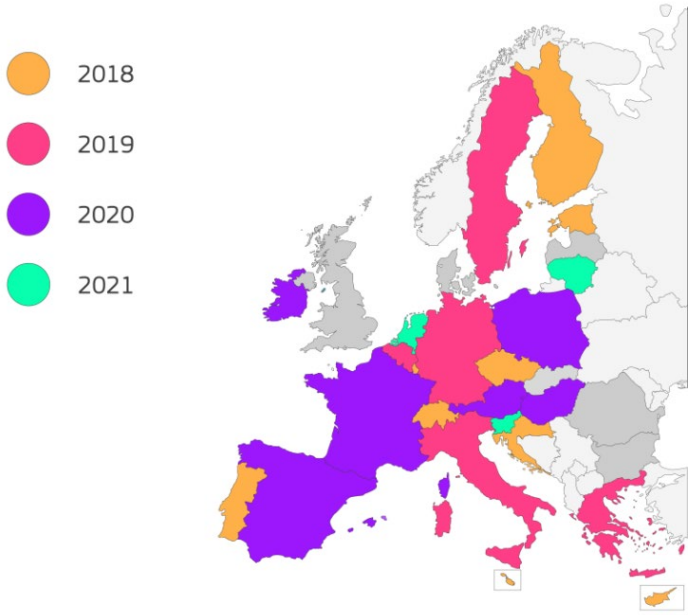
Jose Valverde
DG Connect
European Commission

Commission Communication COM (2018) 233

Digital transformation of health and care *in the Digital Single Market empowering citizens and building a healthier society*



(I) Giving citizens better access to their health data



The eHealth Digital Service Infrastructure (eHDSI) enables exchange of patient data across borders

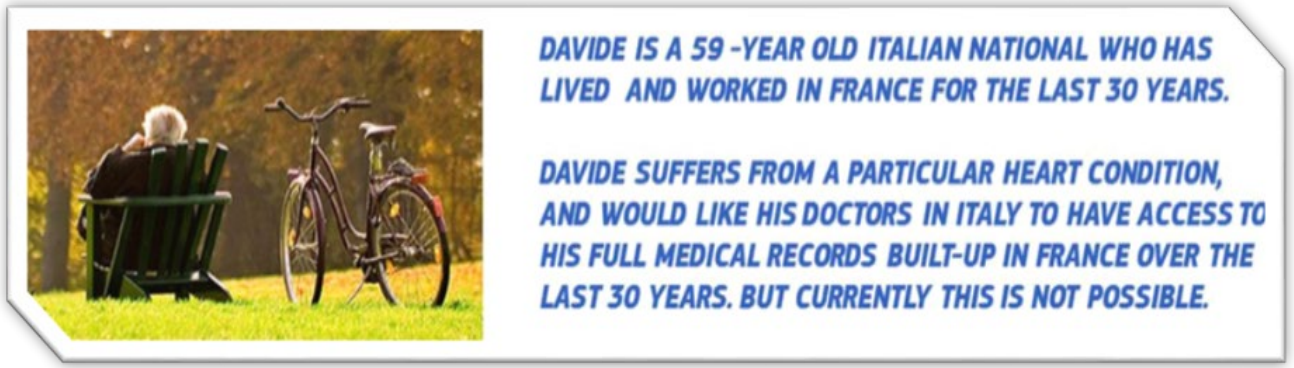
- ***Patient Summary*** *provides access to health professionals to verified key health data of a patient during an unplanned care encounter while abroad*
- ***ePrescription*** *enables patients to receive equivalent medication while abroad to what they would receive in their home country*

(I) Giving citizens better access to their health data

EC encourages and support MS to adopt interoperable electronic health records systems

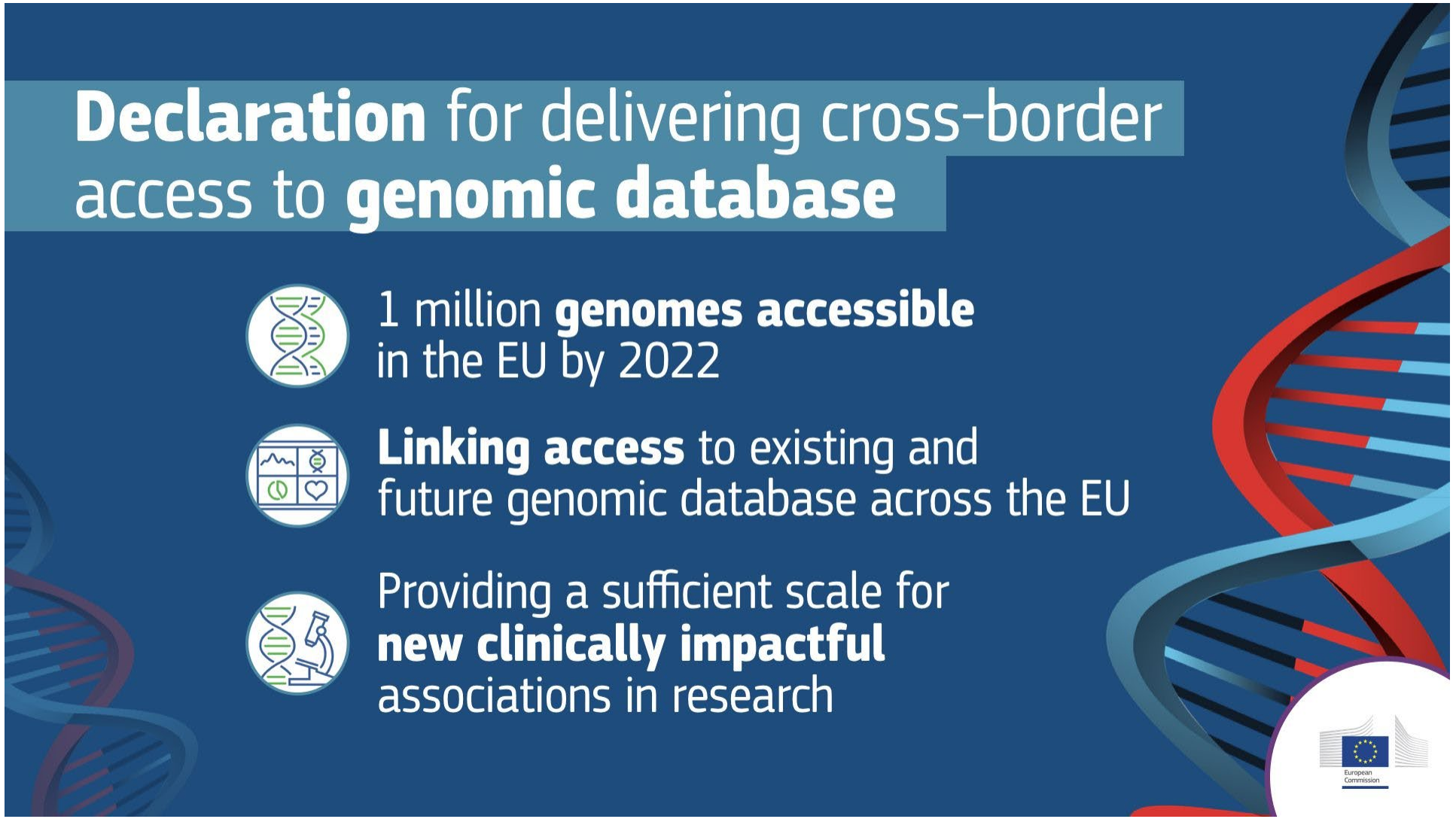
Recommendation

European Electronic Health Record exchange format



(II) Pooling health data for research and personalised medicine

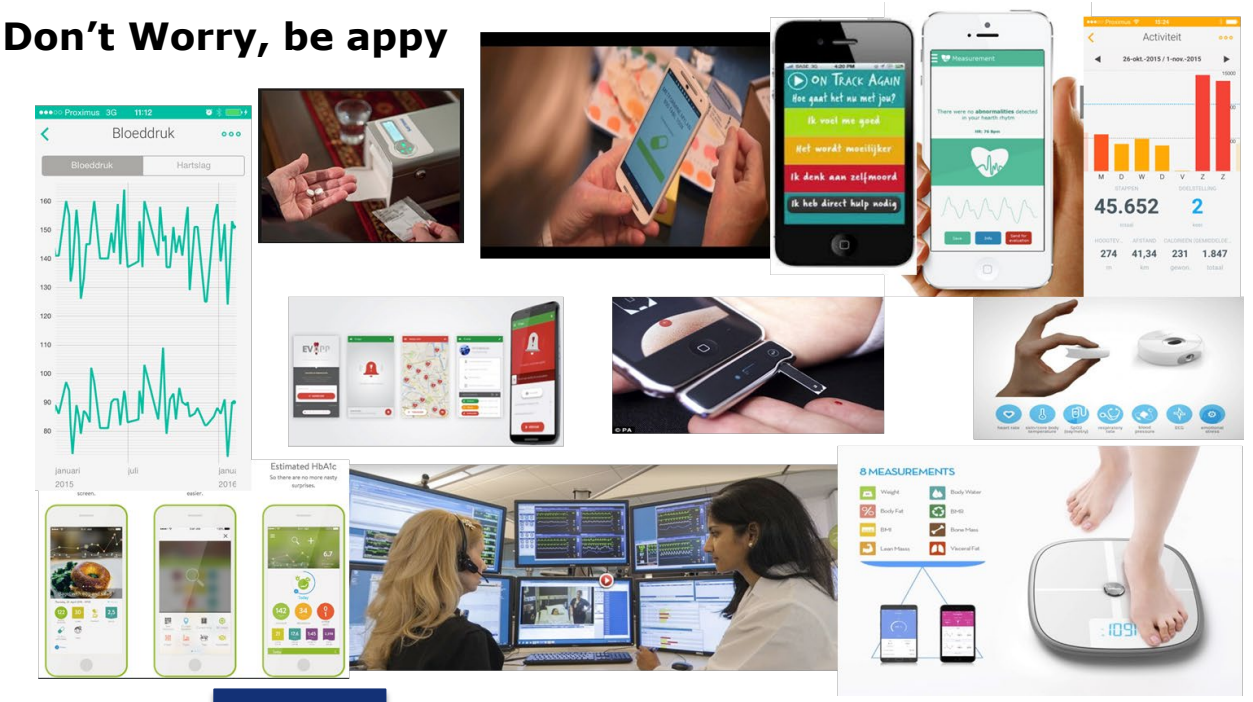
- *Policy coordination, linking resources*
- *Support common data infrastructure, standards*


Declaration for delivering cross-border access to genomic database
1 million genomes accessible in the EU by 2022
Linking access to existing and future genomic database across the EU
Providing a sufficient scale for new clinically impactful associations in research

(III) Digital tools to foster citizen empowerment and person-centred care

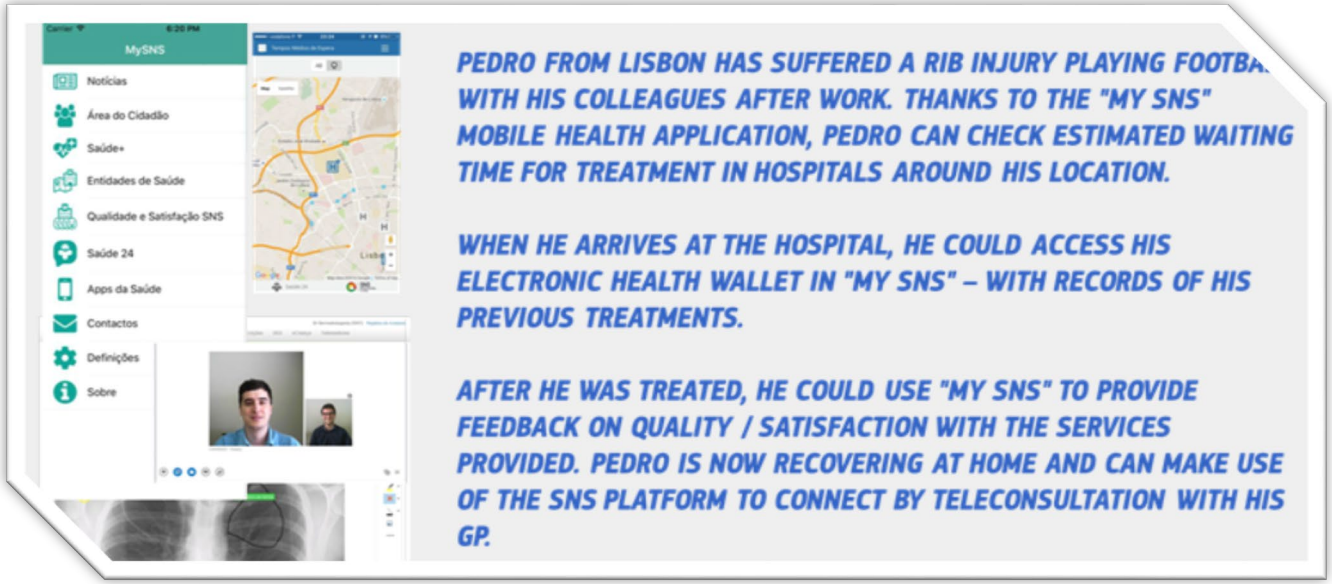
By allowing feedback communication and interaction between users and health care providers, mhealth can improve quality of services and better planning/ management by healthcare systems.

Don't Worry, be appy



(III) Digital tools to foster citizen empowerment and person-centred care

- *Deployment of digital services, capacity building*
- *Common principles for validation and certification*
- *Mobilise investments supporting large scale pilots*



THANK YOU!

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Health Data, Health Data, and More Health Data: From Quantity to Quality Through Cooperation

Wim Goettsch, PhD
Utrecht University
Utrecht, Netherlands

Next Generation Health Technology Assessment

Wim Goettsch PhD

WHO Collaborating Centre for Pharmaceutical Policy, Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht University and Clinical Pharmacology and National Health Care Institute, The Netherlands (ZIN)

Utrecht University

Reasons for changing concepts of HTA

- **Internationalization**
  - Clinical assessments on an European level
  - Alignment with stakeholders (patients, regulators, payers, clinicians)

- **Real world data**

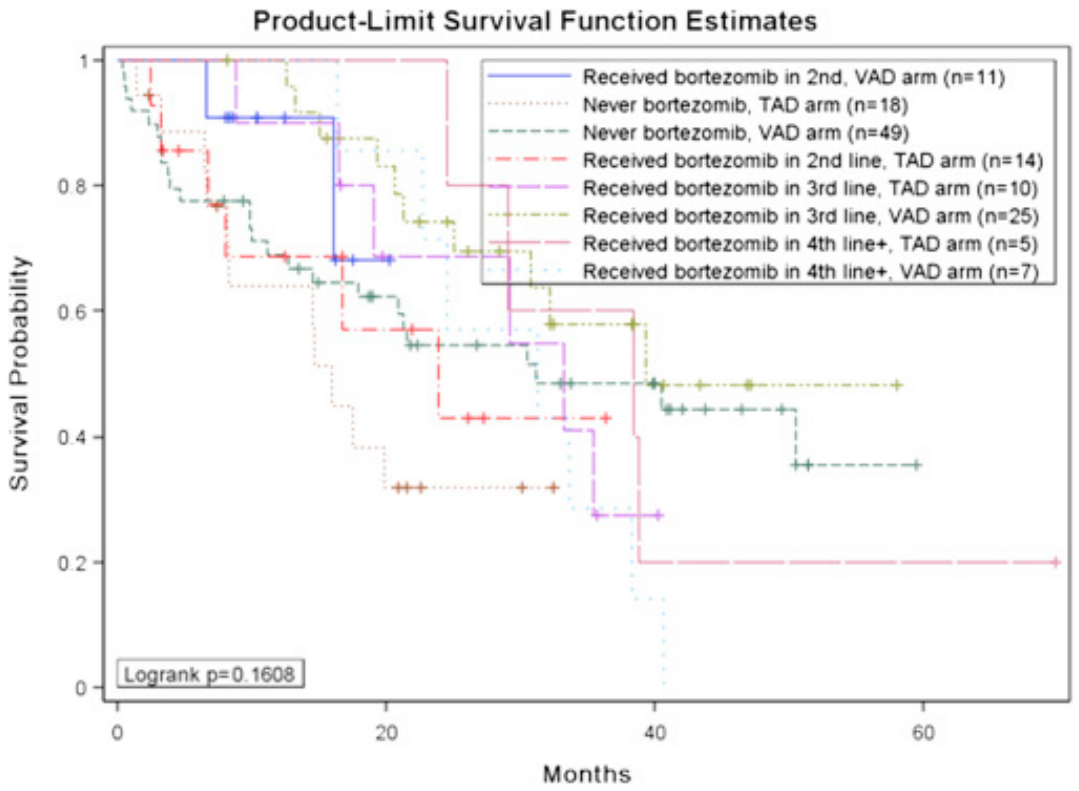
- **Personalized treatments**
  - Smaller populations
  - Combinations of treatments, different sequences
  - Companion diagnostics (genetic testing)

Utrecht University

Development of more personalized treatment concepts

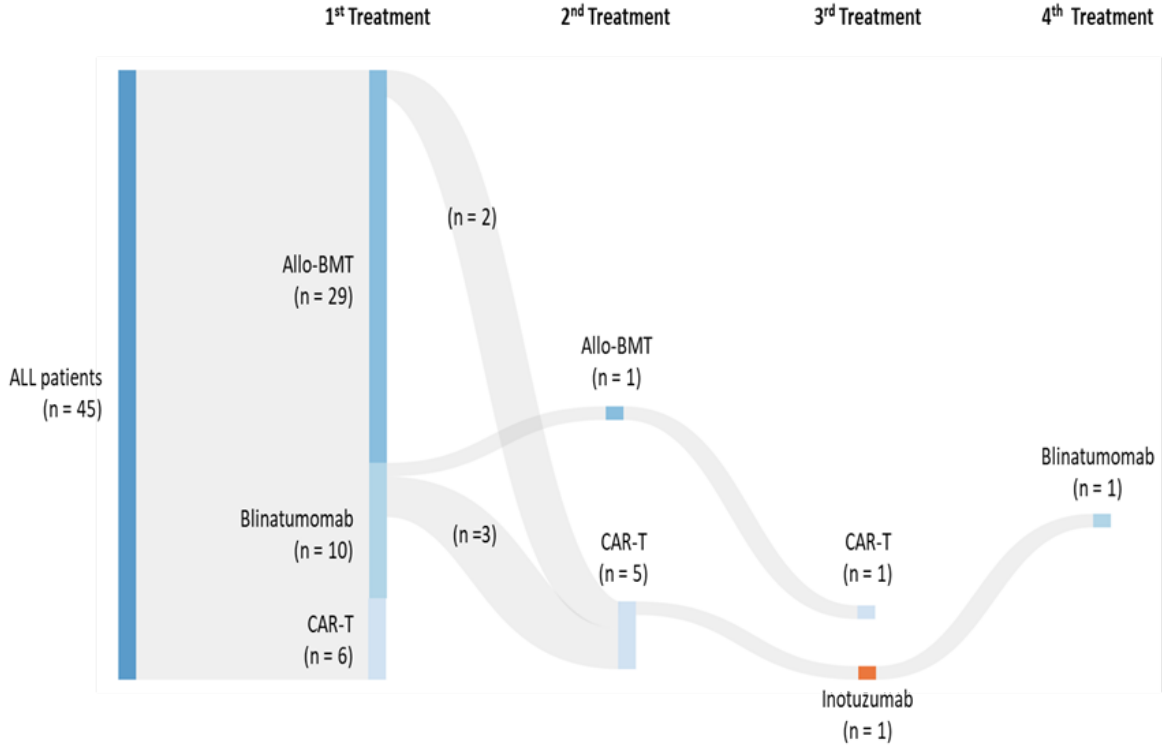
This is the reality for patients

Example 1: Bortezomib treatment in practice (NL)



Franken, MG. et al. Policymaker, Please Consider Your Needs Carefully: Does Outcomes Research in Relapsed or Refractory Multiple Myeloma Reduce Policymaker Uncertainty Regarding Value for Money of Bortezomib? Value in Health 2014, Volume 17 , Issue 2 , 245 - 253

Example 2: CAR-T treatment in practice (USA)



Schulthess D, Gassul D, Makady A etal. Assessment of Chimeric Antigen T-cell Therapy (CAR-T). Effectiveness in practice. "Drug Information Association (DIA) Congress, Boston, June 2018

HTx: Vision for a new generation of HTA

- Imagine an individual patient who visits the doctor for a medical problem. The **doctor knows this patient's clinical history** (including her use of different health technologies, such as medical devices, e-health technologies and drugs), **her preferences and health outcomes**.
- Adequate clinical studies and real-world data analysis have resulted in a **real-time decision support system that the doctor and the patient can use to obtain person-centered information** (in a user-friendly format) about risks, benefits, outcomes and costs associated with a range of possible strategies to manage the patient's ailment.
- The **same information is made available to HTA agencies whose decisions are informed by means of this information**, analysed at the level of individuals and summarised at the subgroup and population level for the benefit of payers' decision-making. **This framework is what we envision as HTx.**

About the HTx project

- HTx is a **Horizon 2020 project** supported by the **European Union**, kicking-off in **January 2019** and lasting for **5 years**.
- HTx will facilitate the development of methodologies **to deliver more customized information on the effectiveness and cost-effectiveness of complex and personalised combinations of health technologies.**
- HTx will also provide methods **to support personalised treatment advice** that will be shared with patients and their physicians.
- Finally, HTx will in close collaboration with the European Network for HTA (EUnetHTA) and its stakeholders **pilot the implementation of these methods in Europe.**

Consortium partners

- **Utrecht University (project coordinator)** (UU) Netherlands
- **University of Copenhagen** (UoC), Denmark
- **University of Oulu** (UoO) Finland
- **University of York** (UoY) UK
- **Medical University of Sofia** (MUS) Bulgaria
- **University of Bern** (UBERN) Switzerland
- **Universidad Politecnia de Madrid** (UPM) Spain
- **European Organisation for Research and Treatment of Cancer** (EORTC) Belgium
- **Dental and Pharmaceutical Benefits Agency** (TLV) Sweden
- **National Health Care Institute** (ZIN) Netherlands
- **National Institute of Health and Care Excellence** (NICE) UK
- **Syreon Research Institute** (SRI) Hungary
- **Synapse research management** (SYNAPSE) Spain
- **EURORDIS Rare Diseases Europe** (EURORDIS) France
- **University of Maastricht (UM)** Netherlands

Advisory boards

HTx Forum:

- to discuss the **broader implications of methods and tools** developed in project for society and healthcare systems.
- senior representatives of the most important stakeholder groups, which are **patients and consumers, payers, healthcare providers, technology producers** and also **regulators and HTA bodies**.

Expert Forum:

- **scientific advisory board** to also assure alignment with other international scientific activities
- representatives of **relevant H2020 (i.e. Impact HTA) and IMI projects (i.e. Prefer, GetReal, EHDEN)**
- representatives from **other organisations that play an important role in setting tools and methods for guideline development** (e.g. ISPOR, Cochrane/GRADE, HTAi, ISPE)

Work Packages

- **WP1** Treatment pathways in specific therapeutic areas
  - General framework for the methods
  - Case studies on **proton therapy head&neck cancer**, **diabetes**, **multiple sclerosis** and **myelodysplactic syndrome (MDS)**
- **WP2** Using real world data (RWD) for Evidence synthesis
- **WP3** Using artificial intelligence (AI) to forecast individualised treatments
- **WP4** Implementation into systems and processes
- **WP5** Transferability and dissemination
- **WP6** Scientific coordination and project management

Next Generation Health Technology Assessment

@htx_h2020

www.linkedin.com/htx_h2020

Utrecht University

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Health Data, Health Data, and More Health Data: From Quantity to Quality Through Cooperation

Guenka Petrova, PhD, DSc
Medical University
Sofia, Bulgaria

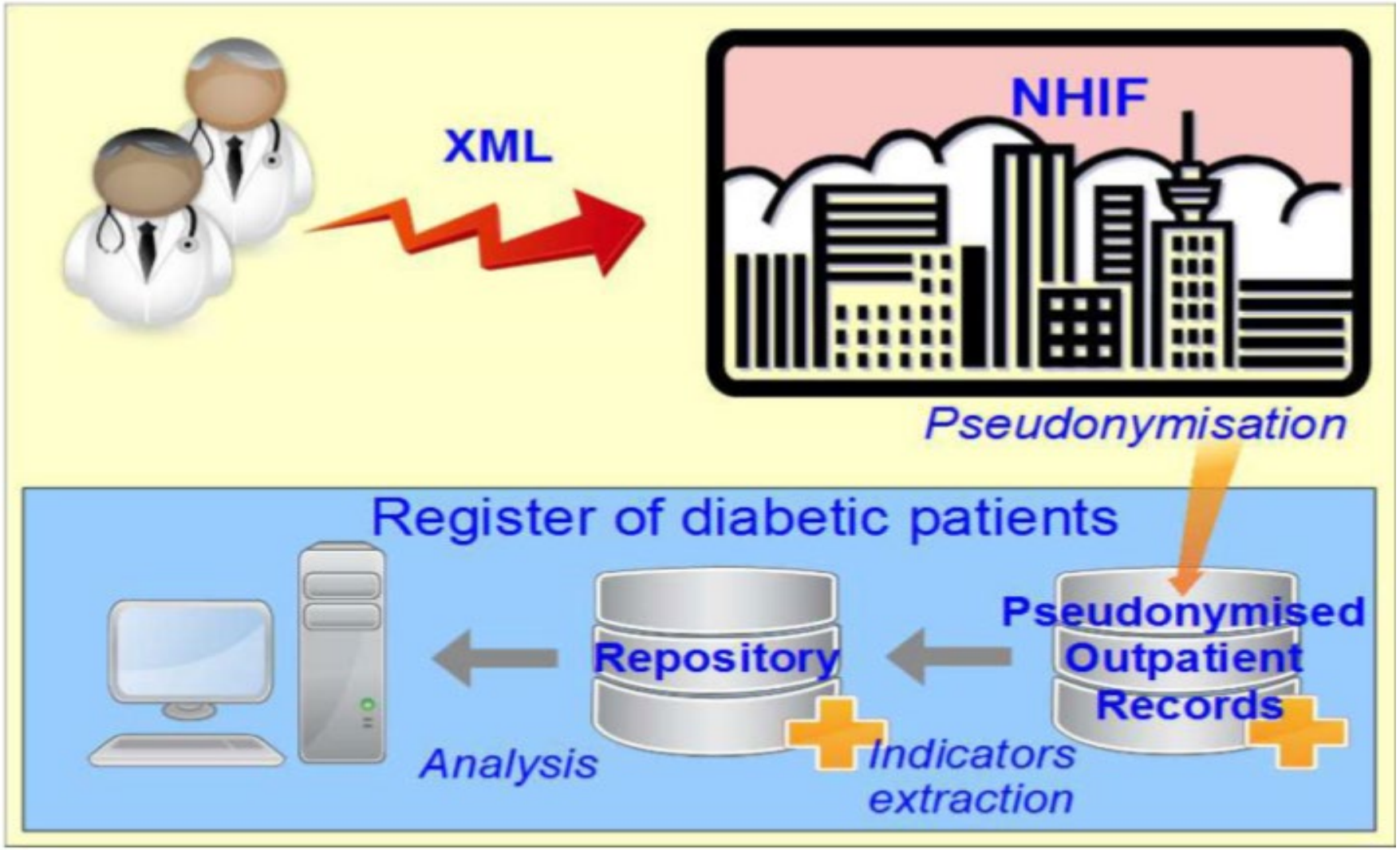
What information the big data analysis could provide – example with diabetes registry

Prof. Guenka Petrova

Diabetes register in Bulgaria

- Developed with a financing support of EU program;
- Publicly accessible;
- Hosted by National University Endocrinology Hospital;
- Contains structured information about millions of examinations, patients records, discharge data etc.;
- Structured XML field provide data about : ·
  - Date and time of the visit ·
  - Pseudonymised personal data, age, gender
  - Pseudonymised visit-related information ·
  - Diagnoses in ICD-10 ·
  - NHIF drug codes for medications that are reimbursed ·
  - A code if the patient needs special monitoring ·
  - A code concerning the need for hospitalization ·
  - Several codes for planned consultations, lab tests and medical imaging.

Development of Bulgarian diabetes register



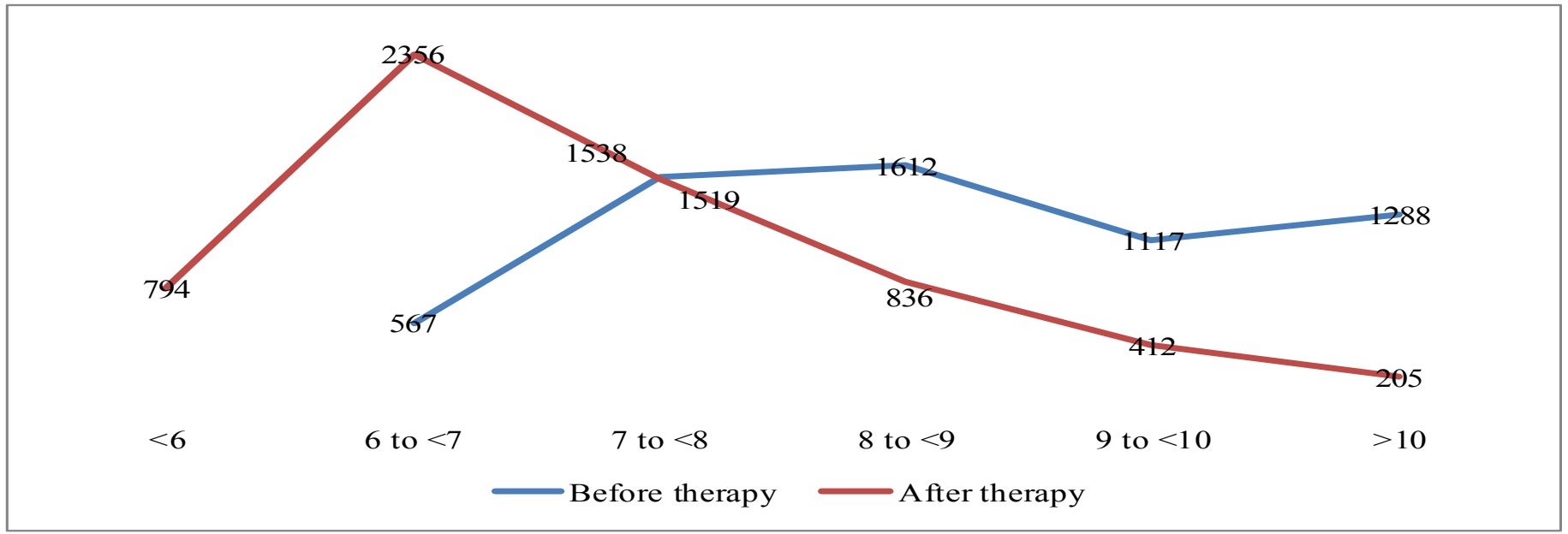
3 years follow up of patients treated with DDP-4i, GLP and SGLT-2i

LETTER TO THE EDITOR

Medical, social, and economic consequences of type 2 diabetes therapy with medicinal products from the group of DPP-4i, SGLT-2i, and GLP-1 RA

- observational study based on the officially reported results for diabetic population therapy with incretin's and SGLT-2i base therapy
- achieved decrease in HbA1c level for one year period.
- includes all patients treated during the period 2012-2016 after the introduction of the therapeutic groups in the practice;
- out of 705 515 records of type 2 diabetic patients 10457 received the analyzed therapy and 6122 perform a decrease in HbA1c level.

3 years follow up of patients treated with DDP-4i, GLP and SGLT-2i



Changes in number patients per HbA1c level before and after the therapy with incretin's and SGLT-2i.

HbA1c decrease in %	DPP-4 i	DPP-4 i + MET	GLP-1 RA	SGLT-2 i	SGLT-2 i+ MET	Total average reduction
Average decrease for 6122 patients with positive clinical result	-1,43	-1,71	-1,76	-1,71	-1,46	-1,67

Reduction in HbA1c according to therapeutic group

3 years follow up of patients treated with DDP-4i, GLP and SGLT-2i

Diabetes incident	Hospital cost	Yearly ambulatory cost	Difference in the number of incidents	Cost for 10 years therapy	Cost for 10 years therapy of incidents according to level of HbA1c	Cost for 10 years therapy of incidents on average
Any end point related to diabetes	600	427.92	58.9	141	287384.88	687967
Death related to diabetes	600	0	46.6	53	27960	31800
All cause mortality	2134	0	40.2	48	85786.8	102432
Fatal and non-fatal myocardial infarction	200	51.22	43.6	47	31051.92	33473
Fatal and non-fatal stroke	650.56	43.13	8.4	10	9087.62	10818.6
Microvascular end points	744	36.38	87.6	113	97043.28	125181.4
Cataract extraction	360	10,08	14,4	15	6635.52	6912
Amputation or death from peripheral vascular disease	2050	20.68	21.0	28	47392.8	63190.4
Heart failure	420	112.72	12.0	10	18566.4	15472
Total cost for 10 years ambulatory therapy and only 1 hospital incident			332.7	465	610 909.22	1 077 247

Cost of avoided diabetic incidents

Quality of diabetes control and its economic implications in Bulgaria

Description	2012	2013	2014	2015	2016
Total number of DM cases	431197	446881	461645	473192	483836
Patients with type-1 DM	28108	27886	27193	26259	25426
Patients with type-2 DM	397154	413331	428972	441199	452490
New cases of type-1 DM	1474	1982	1722	1613	1538
New Cases of type-2 DM	72973	75120	75447	71948	71331

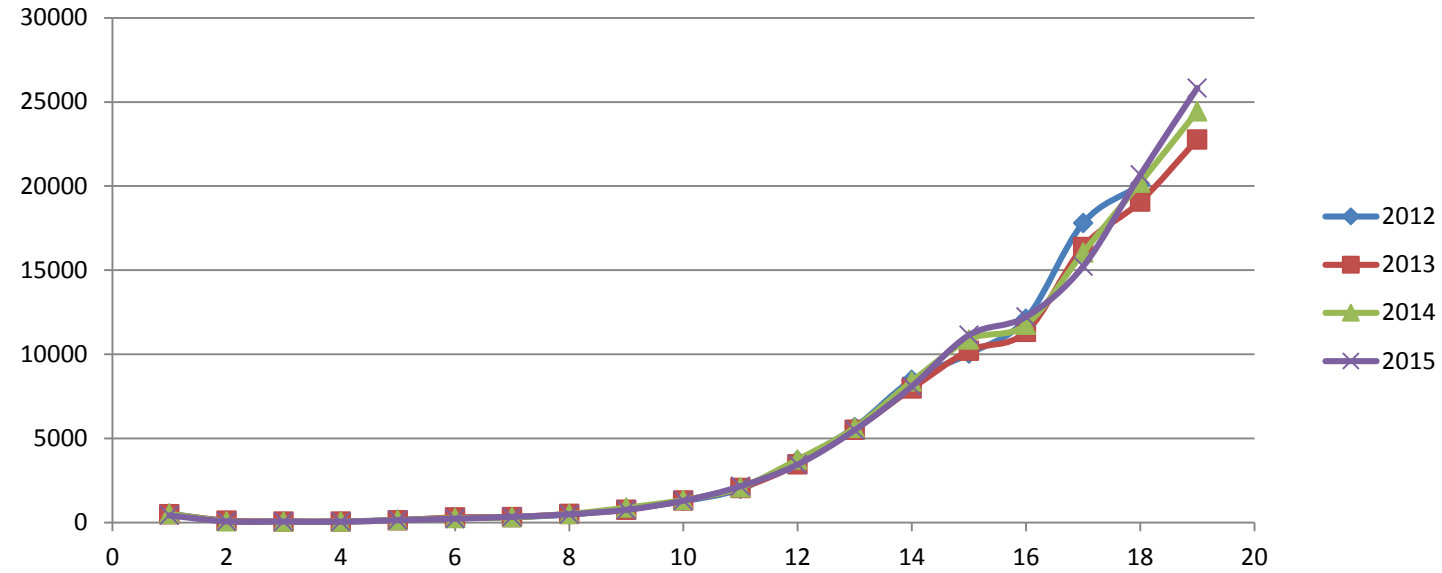
BMI (as per available data)	2012	2013	2014	2015	2016
> 30	23,79	24,01	24,06	23,76	24,05
> 35	11,22	11,32	11,58	11,85	12,39

Indicator	2012	2013	2014	2015	2016
Patients with HgA1c below 7% with type-1 DM (%)	24,6	23,89	27,69	33,88	32,44
Patients with HgA1c below 7% with type-2 DM (%)	41,68	40,05	42,52	44,13	43,91

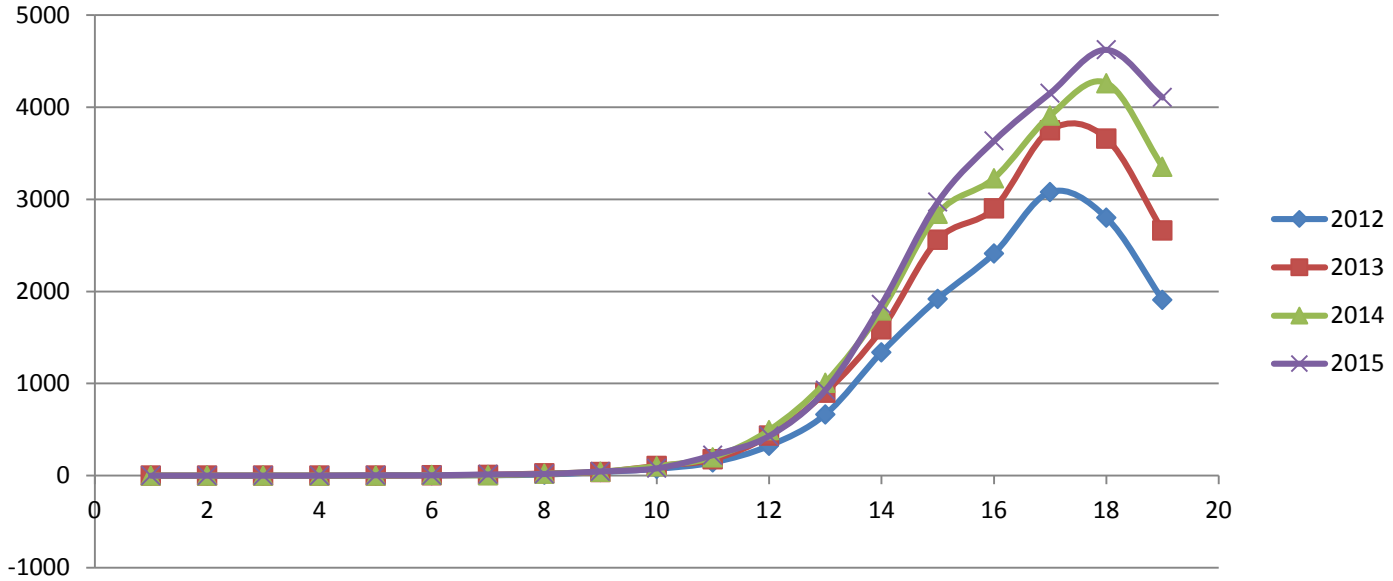
Quality of diabetes control and its economic implications in Bulgaria

Year	2012	2013	2014	2015	2016
Total number of diabetics with at least 2 measurements of HbA1c	92748	103592	107477	127916	155288
Men	41882	46913	48490	58219	10430
Women	50866	56679	58987	69697	144858
Average age (SD)	63(13,06)	63 (13.08)	63.02(13.02)	63 (9,6)	64 (9,5)
Type of diabetes					
Type 1 Diabetes (ICD code E10)	10784	11133	10390	10056	10430
Type 2 diabetes (ICD code E11)	81669	92110	96703	117417	144048
Malnutrition diabetes (ICD code E12)	3	3	2	3	3
Other identified diabetes (ICD code E13)	6	15	9	8	18
Other unidentified diabetes (ICD code E14)	286	331	373	432	790
HbA1c-1 (SD)	7,63 (1,88)	7.6 (1.82)	7.501(1.81)	7,5 (1,34)	7,4 (1,35)
HbA1c-2 (SD)	7,59 (1,85)	7.5 (1.77)	7.45(1.75)	7,4 (1,32)	7,3 (1,32)
HBA1c- average diff. (SD)	0,05 (1,11)	0.08 (1.23)	0.048 (1.2)	0,06 (0,59)	0,07 (0,46)
Number of patients with increases in HbA1c	15509	26863	25135	33154	32135
Number of patients with decreases in HbA1c	17869	22364	26812	29071	26360
Number with no change	59370	54365	55530	65691	96793
Average increase (SD)	1,24 (0,35)	1.3 (1.33)	1.26 (0.81)	1,2 (0,87)	1,19 (0,89)
Average decrease (SD)	1,33(0,88)	0.08 (1.23)	1.14 (0.93)	1,1 (0,8)	1,04 (0,77)

Survival analysis



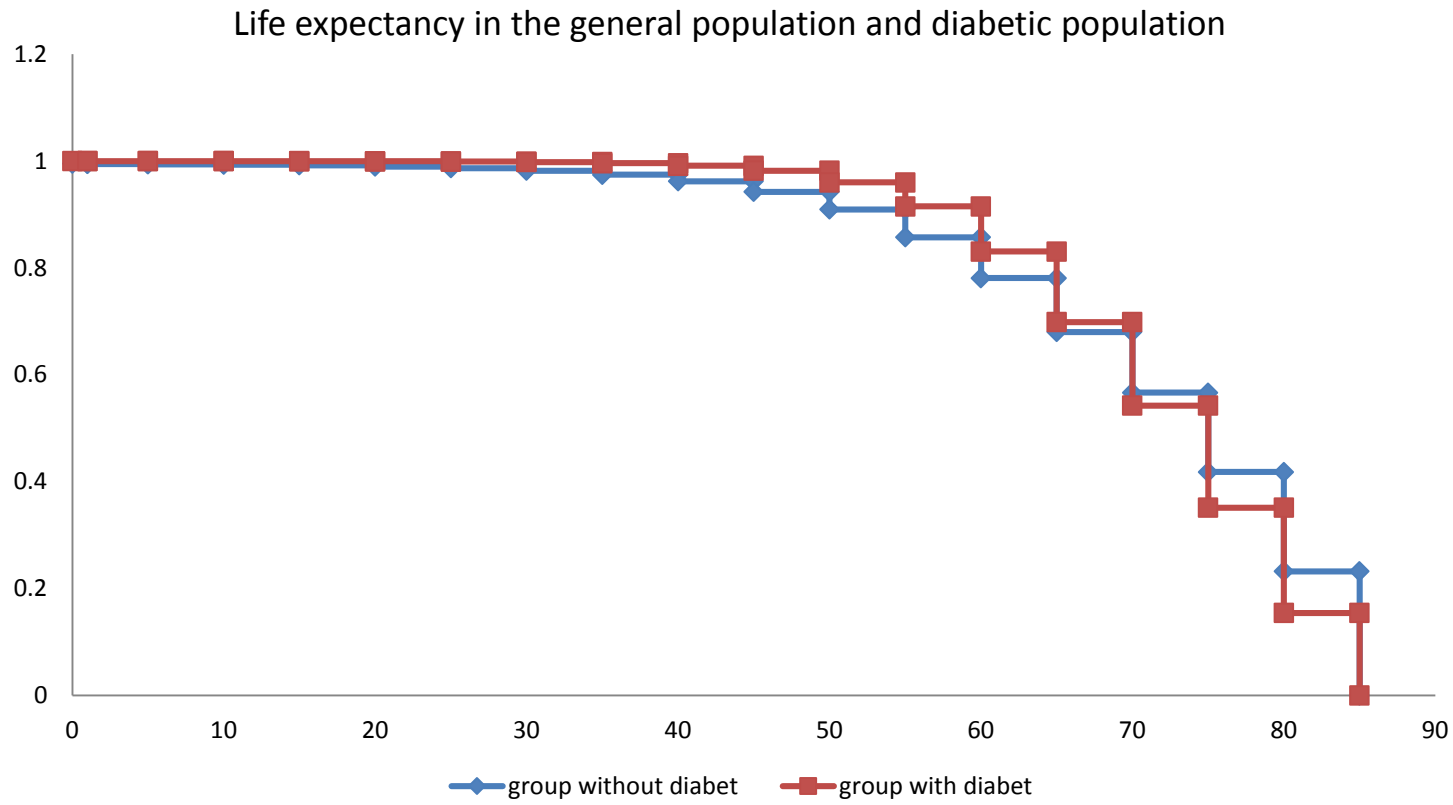
Tendency in the mortality in the general population for the observed period 2012-2015r. (NSI)



Tendency in the mortality in the diabetes population for the observed period 2012-2015r. (National Diabetes Register)

Survival analysis

	2012	P-value	2013	P-value	2014	P-value	2015	P-value
LE in type 1 diabetes	70,05	<0,0001	69,78	<0,0001	70,43	<0,0001	70,96	<0,0001
LE in type 2 diabetes	74,2	0,067	74,34	0,001	74,59	0,0002	75,19	<0,0001
LE in the general population	73,96		73,97		74,18		74,55	



Survival in diabetic patients group and in general population (without endocrine diseases)

Conclusions

- Registers should be regularly analyzed;
- They provide valuable information for clinicians:
  - About the level of control achieved;
  - About the effectiveness of therapy;
  - Many possibilities for subgroup analysis;
  - Life expectancy and survival as long term results.
- They also provide valuable information for health care authorities about the economic impact of new therapies.

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Health Data, Health Data, and More Health Data: From Quantity to Quality Through Cooperation

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Challenges of data standardization and governance across borders

Dr. Alexander Berler
Director Consulting Services,
Gnomon Informatics SA

ISPOR
Improving healthcare decisions

27-28 March 2019 | Warsaw, Poland

The Challenge

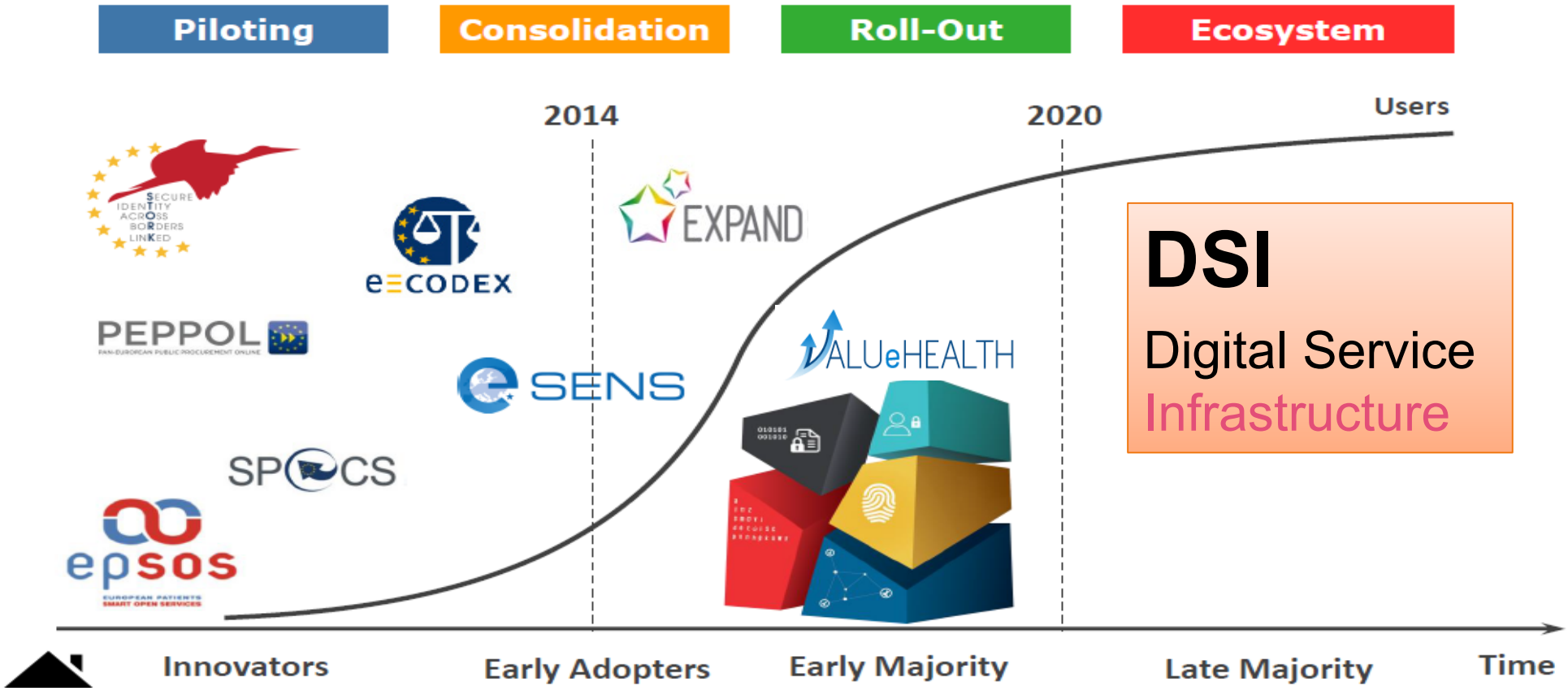
What if you had a cell phone plan that only allowed you to call other customers of your carrier?

That's the situation for most healthcare providers today, when they join a data sharing network.

European context

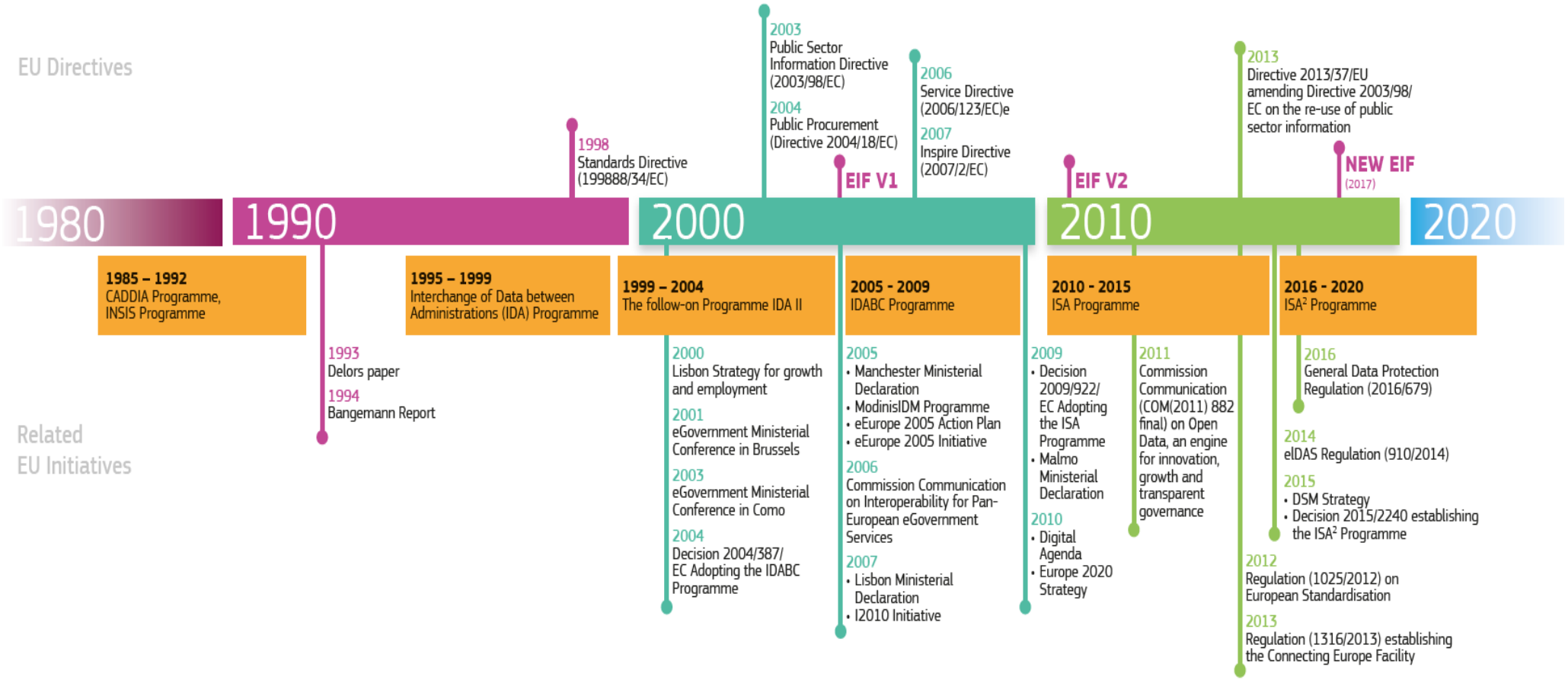
Creating a #DigitalSingleMarket

The building blocks represent a massive investment since their creation by the Large Scale Pilots. As their user base grows, the Commission is already working on their sustainability beyond CEF.

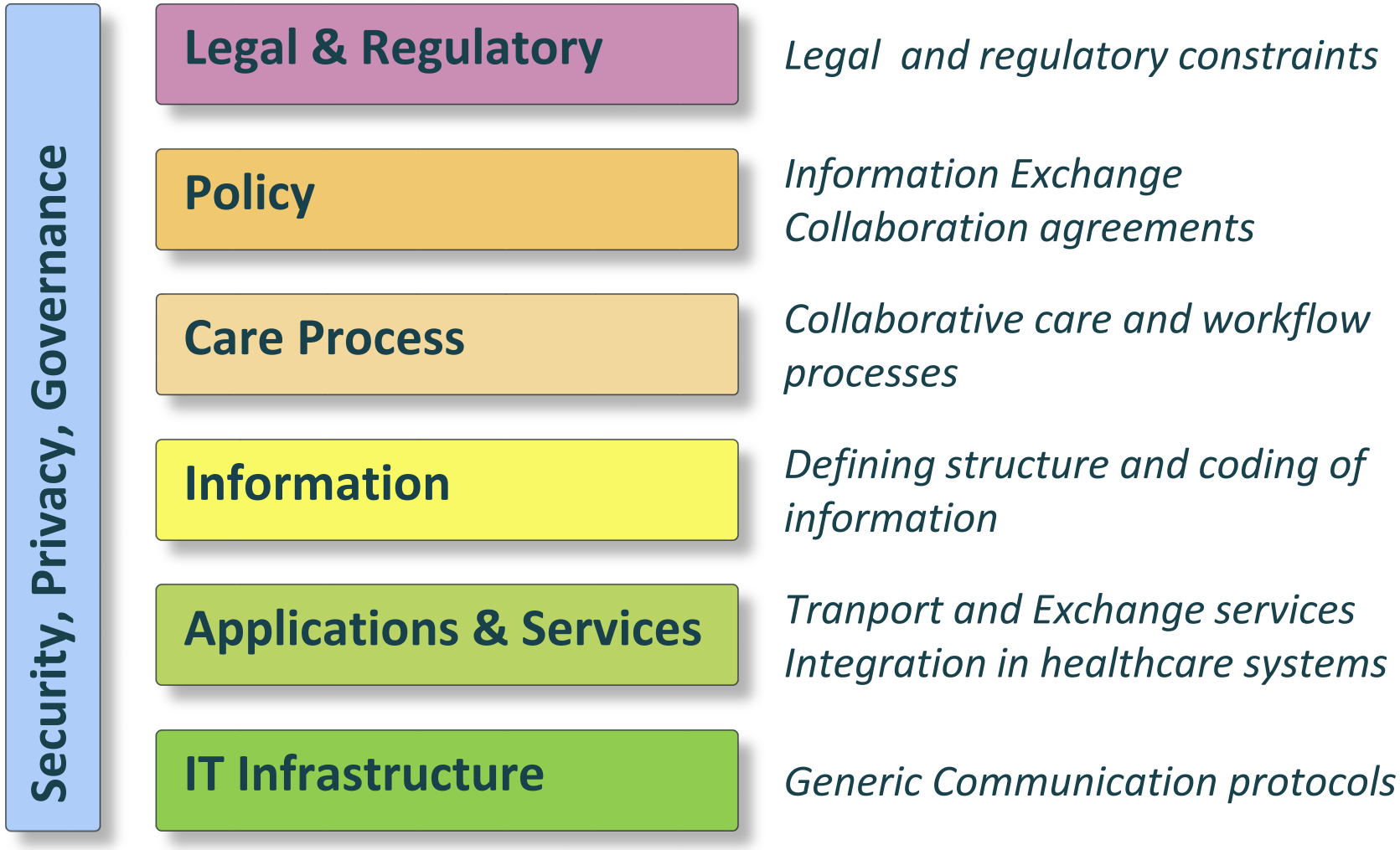


Source: Gerald Cultot, European Commission, Keynote speech at IHE World Summit 2016

EUROPEAN **INTEROPERABILITY** TIMELINE



The many dimensions of Interoperability



Legal and regulatory constraints

Information Exchange
Collaboration agreements

Collaborative care and workflow processes

Defining structure and coding of information

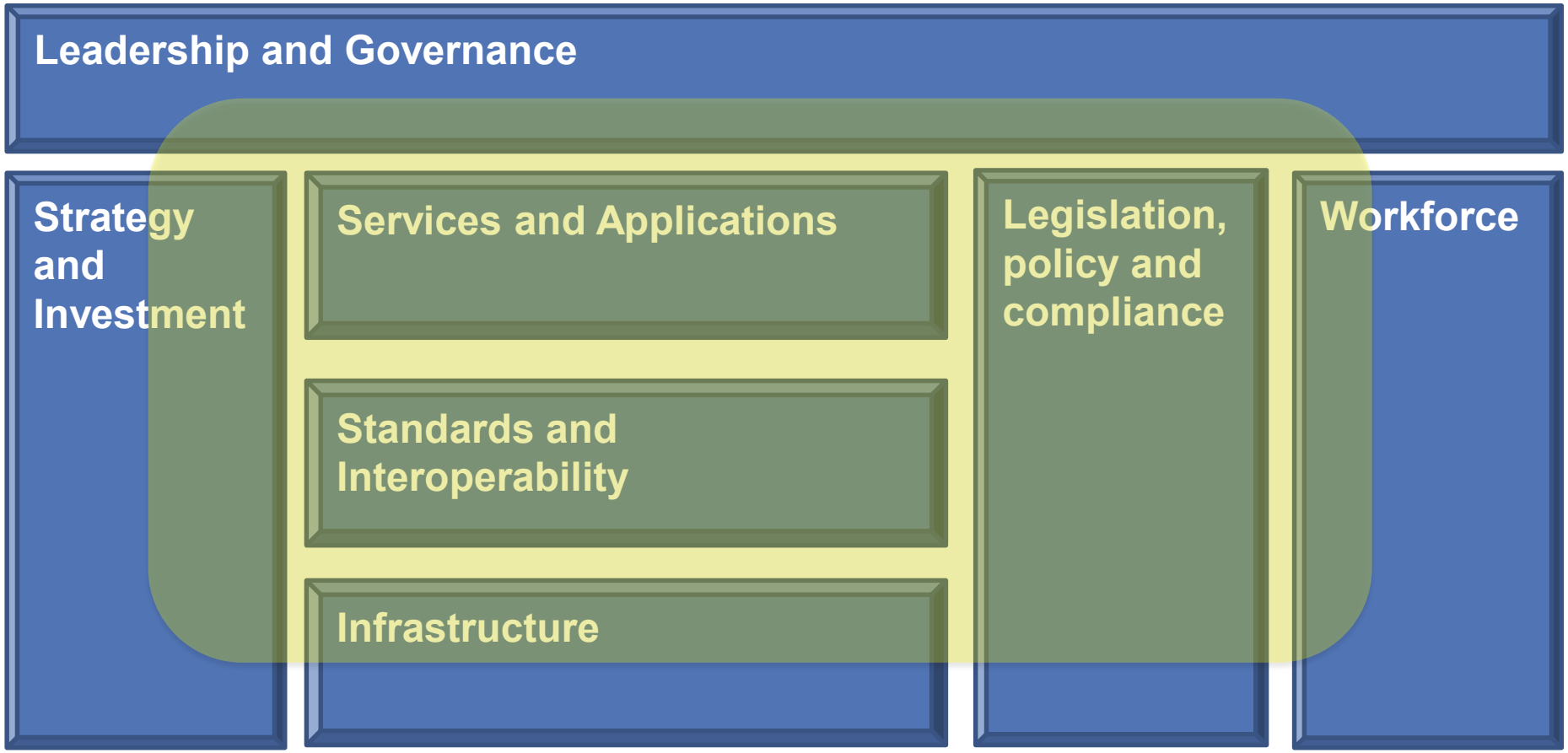
Tranport and Exchange services
Integration in healthcare systems

Generic Communication protocols

From Refined ehealth European Interoperability Framework EU eHealth Network, 23/10/2015

Components of a National/Regional ehealth Strategy

What components contribute to interoperability ?



From National ehealth Strategy Toolkit – WHO – ITU - 2012

Use case driven approach

Key Challenges and User Needs	
1	Describe User needs for today and tomorrow
2	Deduce Interoperability Use cases
3	Analyze your current infrastructure

1

Select Use Cases	
1	Define your criteria selection
2	Define your eHealth roadmap
3	Select your use cases

2

"Clear policies" for:
- ➔ Privacy and security
- ➔ Governance rules for implementation (e.g. testing and conformity assessment)
- ➔ Govern evolution of the framework

Define your implementation	
1	Define your governance (distribution of responsibilities between technical and organisational level
2	Describe your interoperability realisation scenarios
3	Select profiles and standards (IOP Framework)
4	Develop corresponding detailled Interoperability Specifications

3

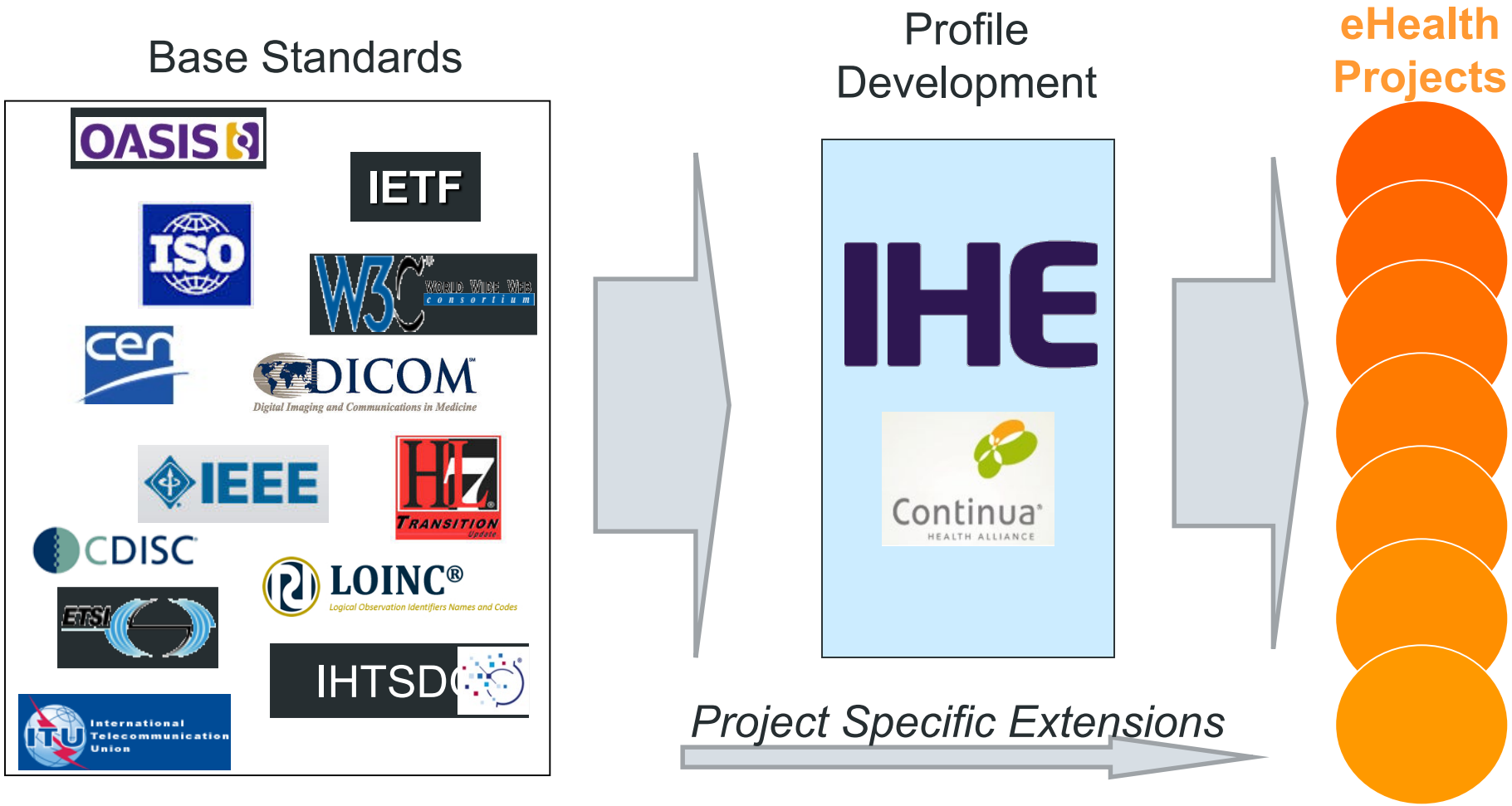
1	Define your testing strategy
2	Define your testing environment
3	Select your test tools

4

Develop your tender	
1	Prepare your budget
2	Write your tender based on your interoperability specifications
3	Validate your tender following EU/National rules

5

Interoperability: From a problem to a solution

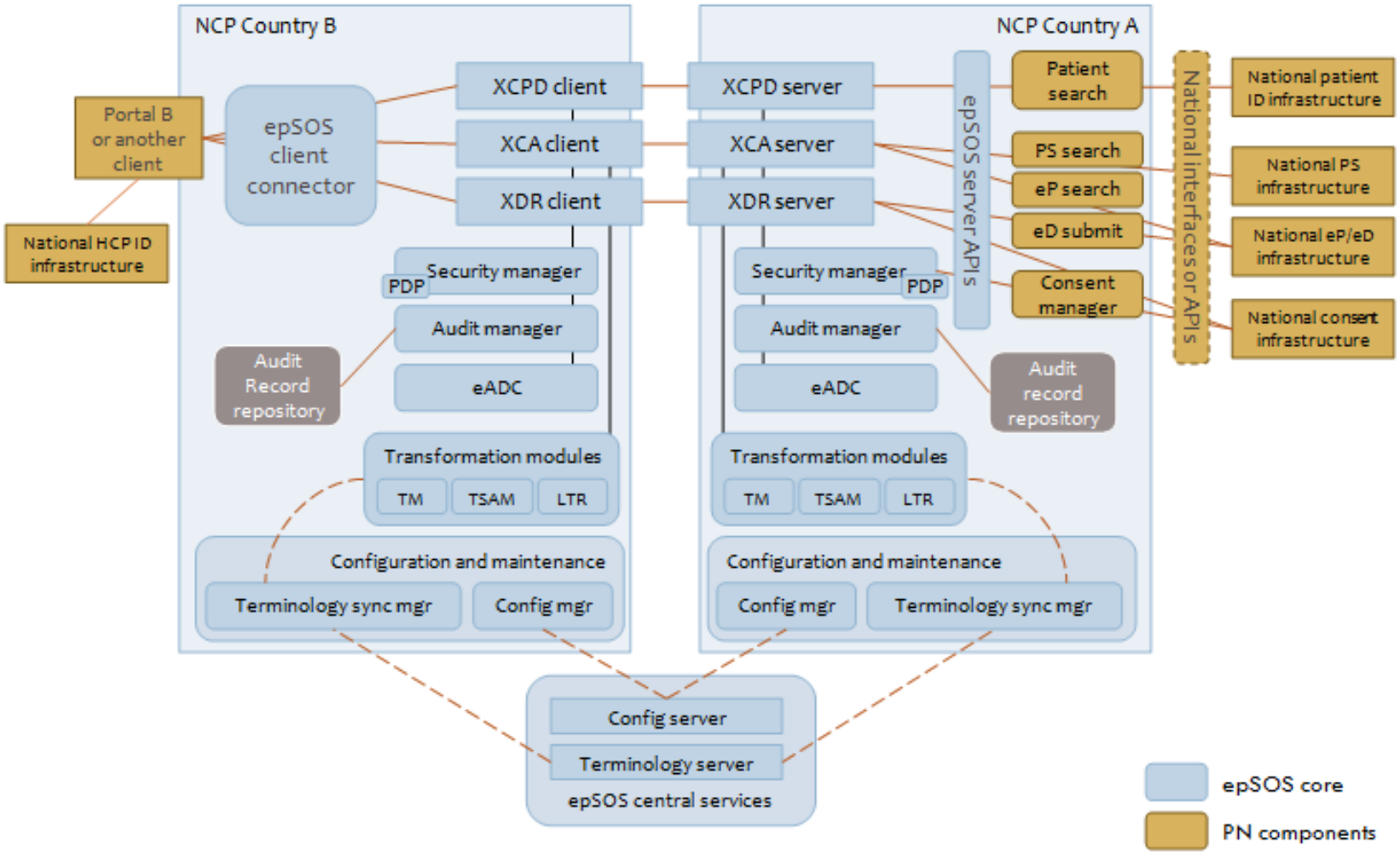


Profiling Organizations Are Well Established

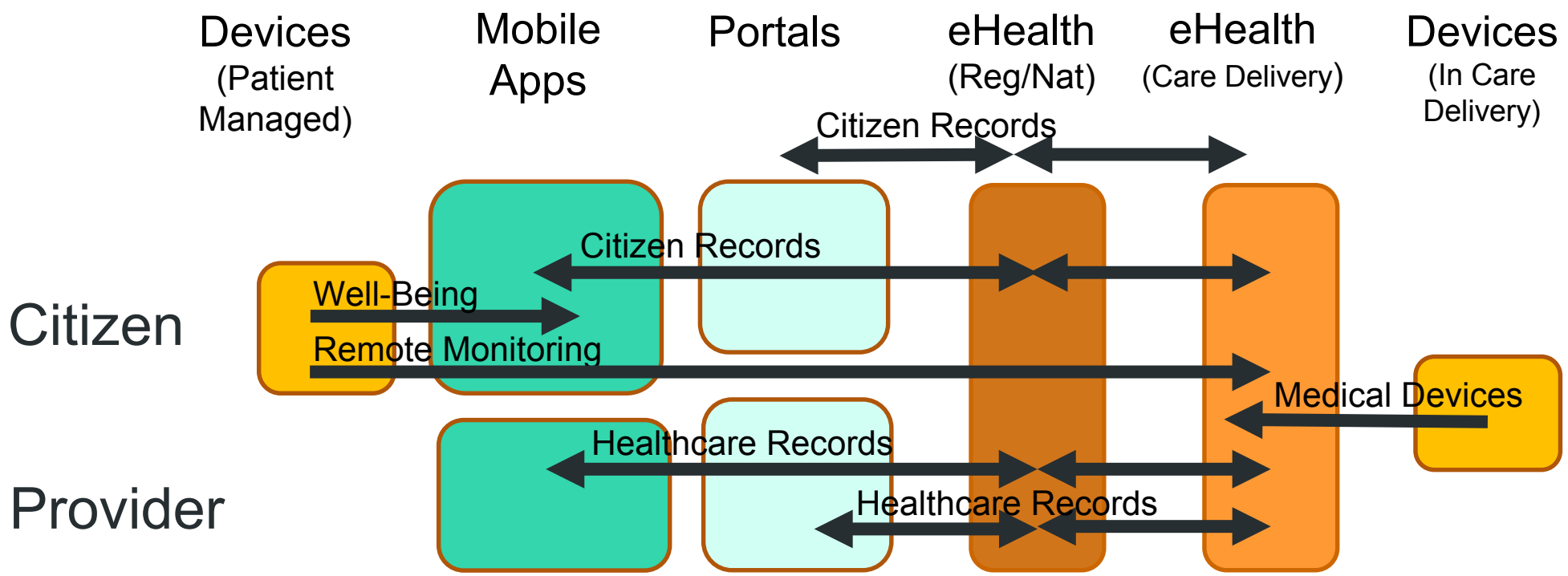
27 IHE Profiles recognized under EU regulation 1025/2012

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2015_199_R_0011

eHDSI Architecture is based on IHE profiles



Next Stop in a future not that far: interconnected healthcare services networks for the benefit of the patient



mHealth, eHealth and Health/Medical Devices as components of the connected health system

gnomon INFORMATICS

Vision

Cross border, Across devices, Across clouds, Frictionless data flow for healthcare and wellness, Direct to Cloud Medical IoT

eHealthPass
Getting charge of your own data

Portfolio

AGENCE eSanté LUXEMBOURG | Agence nationale des informations partagées dans le domaine de la santé

abrumet

mita MALTA INFORMATION TECHNOLOGY AGENCY

enisa European Network and Information Security Agency

eHealth Ireland

Servicio Murciano de Salud

Swiss Confederation

Agència de Qualitat i Avaluació Sanitàries de Catalunya

Sveriges Kommuner och Landsting

ISST Institut Software- und Systemtechnik

IHE EUROPE

SPMS EPE Serviços Partilhados do Ministério da Saúde

giz Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

MINISTERIUM FRAUEN GESUNDHEIT

HAIKA ΗΛΕΚΤΡΟΝΙΚΗ ΔΙΑΚΥΒΕΡΝΗΣΗ ΚΟΙΝΩΝΙΚΗΣ ΑΣΦΑΛΙΣΗΣ Α.Ε.

T.C. Sağlık Bakanlığı

SORESA Soggetto Aggregatore della Regione Campania

LOMBARDIA INFORMATICA

Standards

HL7® FHIR®

Personal Connected Health Alliance

IHE Integrating the Healthcare Enterprise

HL7 INTERNATIONAL

CEN Health Informatics TC251

IPS compliance, made for the EHRxF

https://www.ehealthpass.gr/

Our Values…

Privacy

Manage privacy and consent, Collect and aggregate data from information sources and the IoT world under patient's control of data usage

Self Management

From IoT to personalised questionnaires and chatbots

Empower the Patient to get in charge of his own data

Interoperability

Support of international standards and EU eHealth interoperability framework

Unlock the value of data for the gain of end users and innovators !

Collaboration

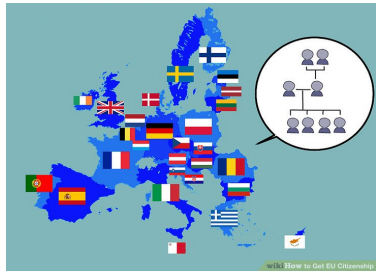
Provide modern patient doctor collaboration tools (Alerts, Reminders, Appointments, Shared care Plans, teleconferences

…Our Future

Medical tourism across borders

Emergency and unplanned care

Chronic Disease Management



Cross border Data for the Citizen

eHealthPass for Diabetes

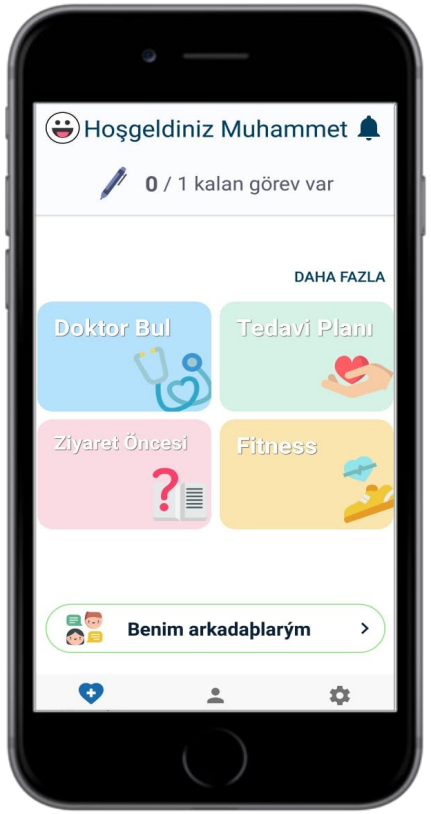
DM4all

Patient View

- Diabetes self-management
- Shared care plan
- Patient empowerment
- Community building
- Continuous education and training
- IoMT Devices
- Diabetes virtual assistant

Professionals View

- Diabetes monitoring
- Increase efficiency
- Predictive and proactive analytics
- Information exchange
- Clinical decision support
- Remote communication and monitoring
- Improve collaboration

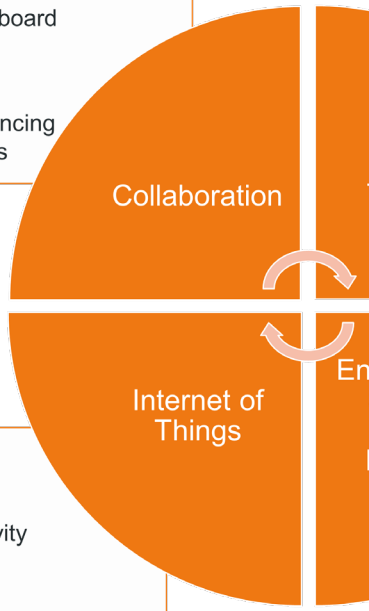


eHealthPass for Chronic Pain

epione
SOOTHING PAIN

- Shared Care Plan
- Doctor's Dashboard
- Virtual Coach (Chatbot) data acquisition
- Video Conferencing
- Questionnaires

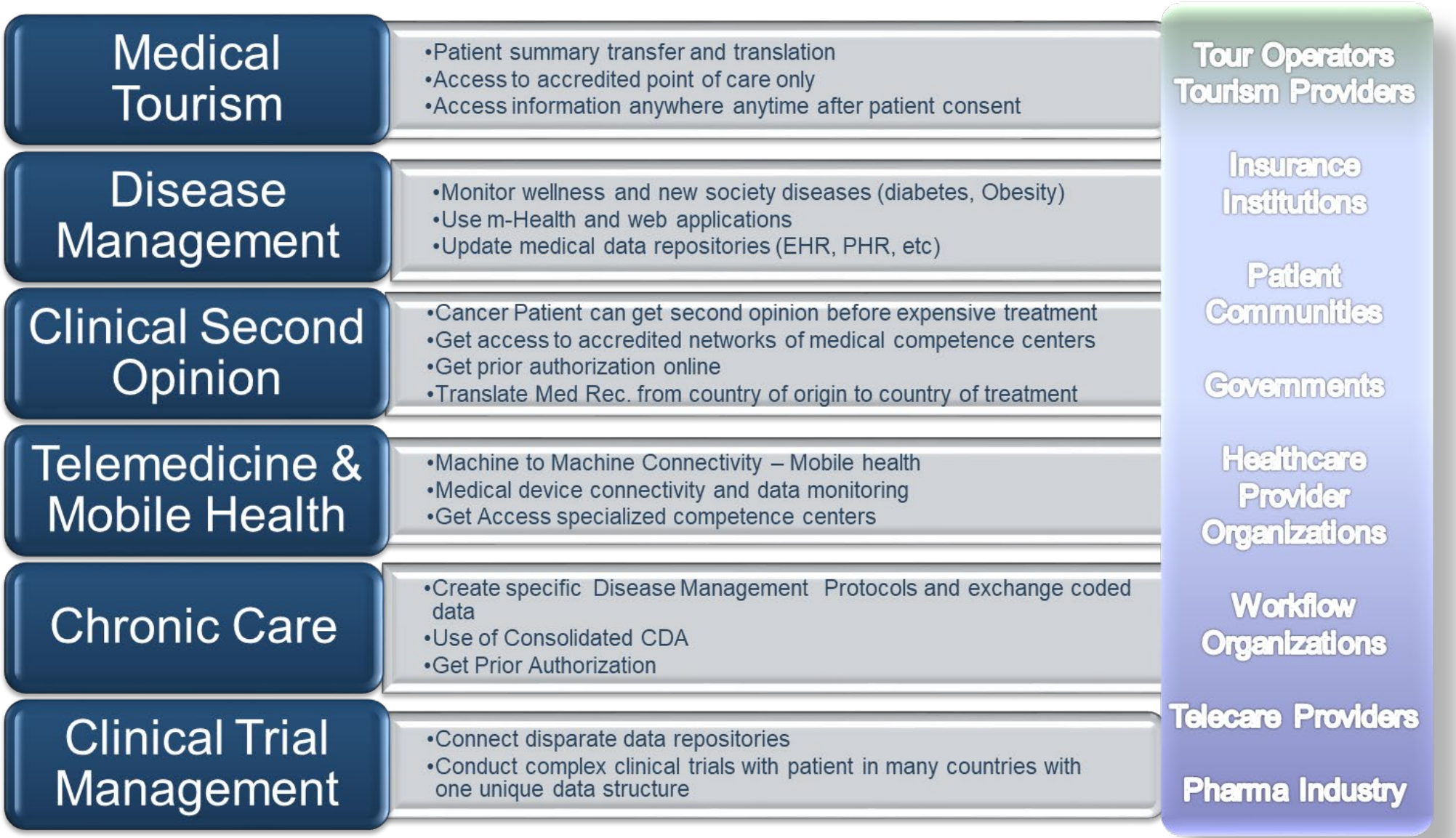
- Virtual Patient
- Timely information presentation



- Sleep
- Physical Activity
- Stress

- User Stories
- Community Portal
- Buddies

Cross Border Healthcare: Healthcare Roaming
Welcome to a new market being born



"The best way to predict the future is to invent it."
Alan Kay

Thank you!

For More Information

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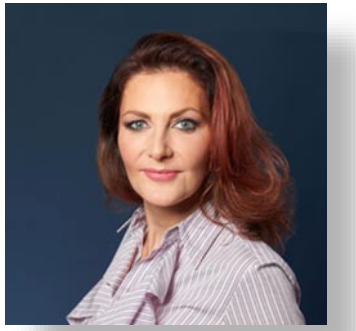
Health Data, Health Data, and More Health Data: From Quantity to Quality Through Cooperation

Alexander Berler Msc, PhD
Gnomon Informatics SA
Athens, Greece

Health Data, Health Data, and More Health Data: From Quantity to Quality Through Cooperation



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