REGIONE DEL VENETO

AZIENDA ZERO

arsenàl.IT
centro veneto ricerca e innovazione per la sanità digitale

Veneto Region eHealth strategy: Interoperability First

Padova, 26th May 2020

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Outline:

1. Introduction: eHealth strategy of the Veneto Region
2. Legal background
3. Regional regulations about Testing process
4. Technical background: HIE
5. Testing & Tools: strategy and roles

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Introduction

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Regional Organization

Veneto Region

REGIONE DEL VENETO

- **Timely and coordinated investments** in innovation
- **Sustainable and clear e-health objectives**
- **Direct collaboration** between Governement and Innovation resources

The Local dimension

- **Coordination between Region and LHAs**
- **60.000 professionals involved** in the 23 LHAs and Hospital Trust
- **IT and organizational solutions as answer to local needs**
- **Support to the new organisation** asset from 21 to 9 LHAs

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Consorzio Arsenàl.IT

Veneto's Research Center for eHealth Innovation

arsenàl.IT
centro veneto ricerca e innovazione per la sanità digitale

Founded in 2005 as "Telemedicine Consortium", currently groups all the 10 Local Health Authorities / 2 Hospital Trusts / 1 Cancer Research Center belonging to the Veneto Region.

The consortium has succeeded in highlighting the critical issues of **interoperability**, **standardization** and **organizational impact** as key factors for driving Telemedicine applications to the mainstream of the care delivery process.

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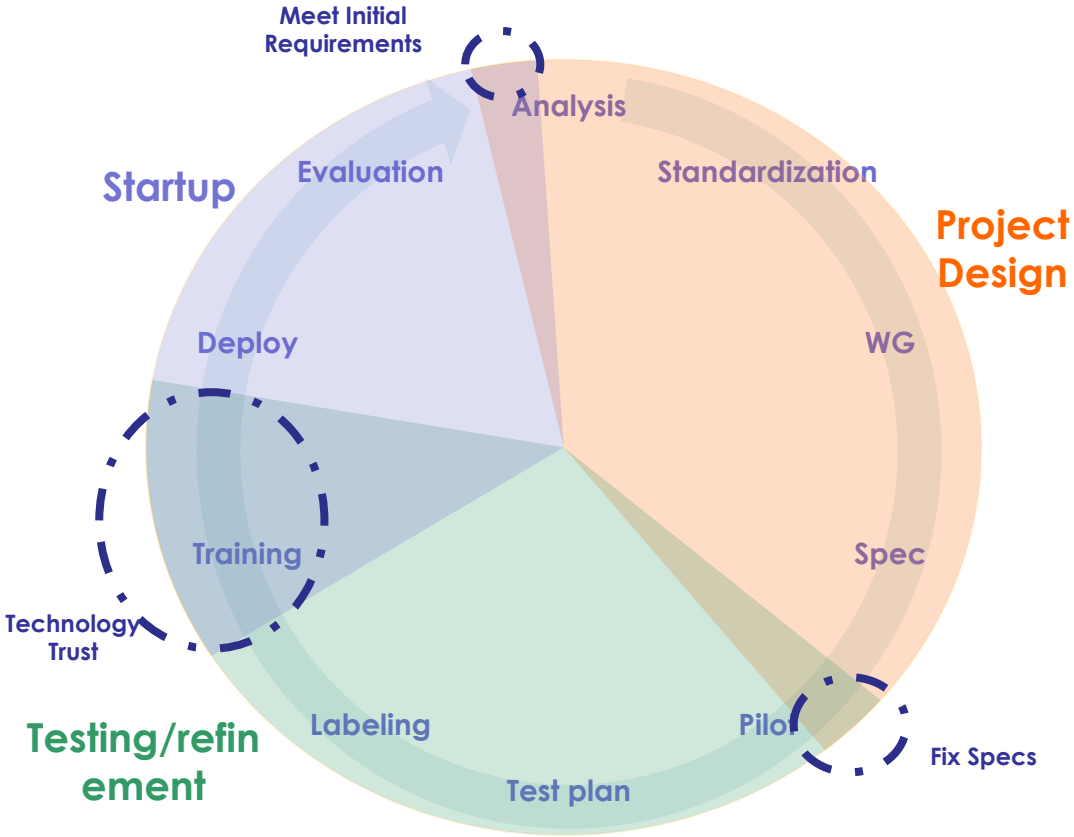
Our Approach to projects



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Interoperability as a MUST

What we can gain choosing international standards:

- **Modularity;**
- **Functional Scalability;**
- **Reduce design costs;**
- **Reduce maintenance costs;**
- **Increase market acceptance;**
- **Freely Available tools;**

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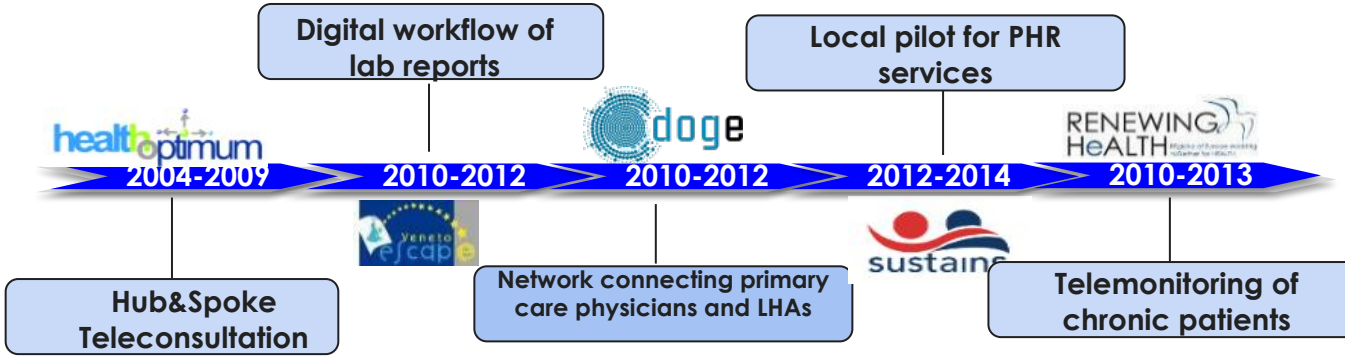
IHE and Arsenàl.IT

- Arsenal.IT is a member of IHE International and IHE Europe
- Active role in definition of profiles: es. XDW profile



Regional HIE

FSE
FASCICOLO SANITARIO ELETTRONICO REGIONALE

IHE Integrating the Healthcare Enterprise

IHE Profile	Use
XDS	Sharing teleconselling docs, lab reports, ePrescription, eReferral, telehomemonitoring summaries
XDS-I	Sharing CT Images
XD-LAB	Lab report structure
EUA/XUA	User security
ATNA	Connection security, audit
XDW	Workflow management
XBeR-WD	eReferral workflow
XTHM-WD	Telehomemonitoring workflow

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THE Project: full HIS Replacement

Amount of clinical operators involved: 70.000

Tender Value: 173.000.000 €

Hospitals involved: 36

The GOAL is to create **new paradigm**: the value added by the HIS is not the data stored but how data are managed/manipulated by the software. So the **software back-end is a standardized regional module** that is used by all the systems in order to share data. All the systems interact in a standardized way sharing clinical and workflow data.

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Legal Background

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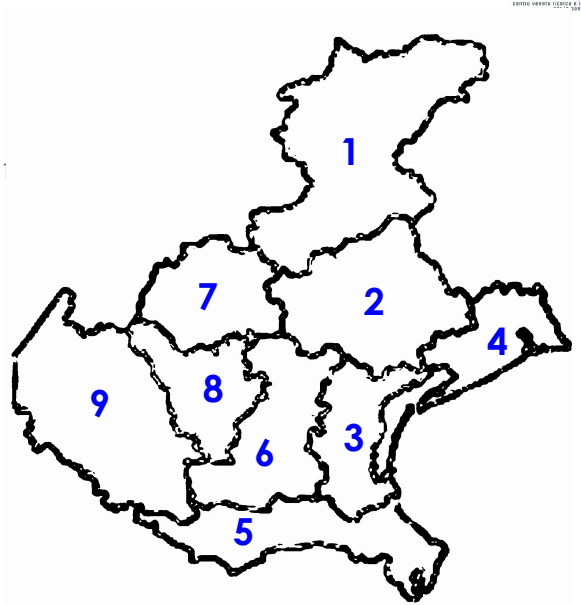
2016 Veneto Region Healthcare Reform
LOADs or OPPORTUNITIEs ?

- In Veneto Region there were 23 Local Health Authorities and 2 Hospital Trust

- Regional Law 19/2016: Creation of an additional institutional-organizational LHA, called "Azienda Zero", in charge of management and control, **technical** and administrative functions

- Unification of Local Health Authorities in 9 Local Health Authorities and 2 Hospital Trust



- Reduce costs for general and common functions at regional level
- Centralize programming and control, distinguishing it from the provision of services

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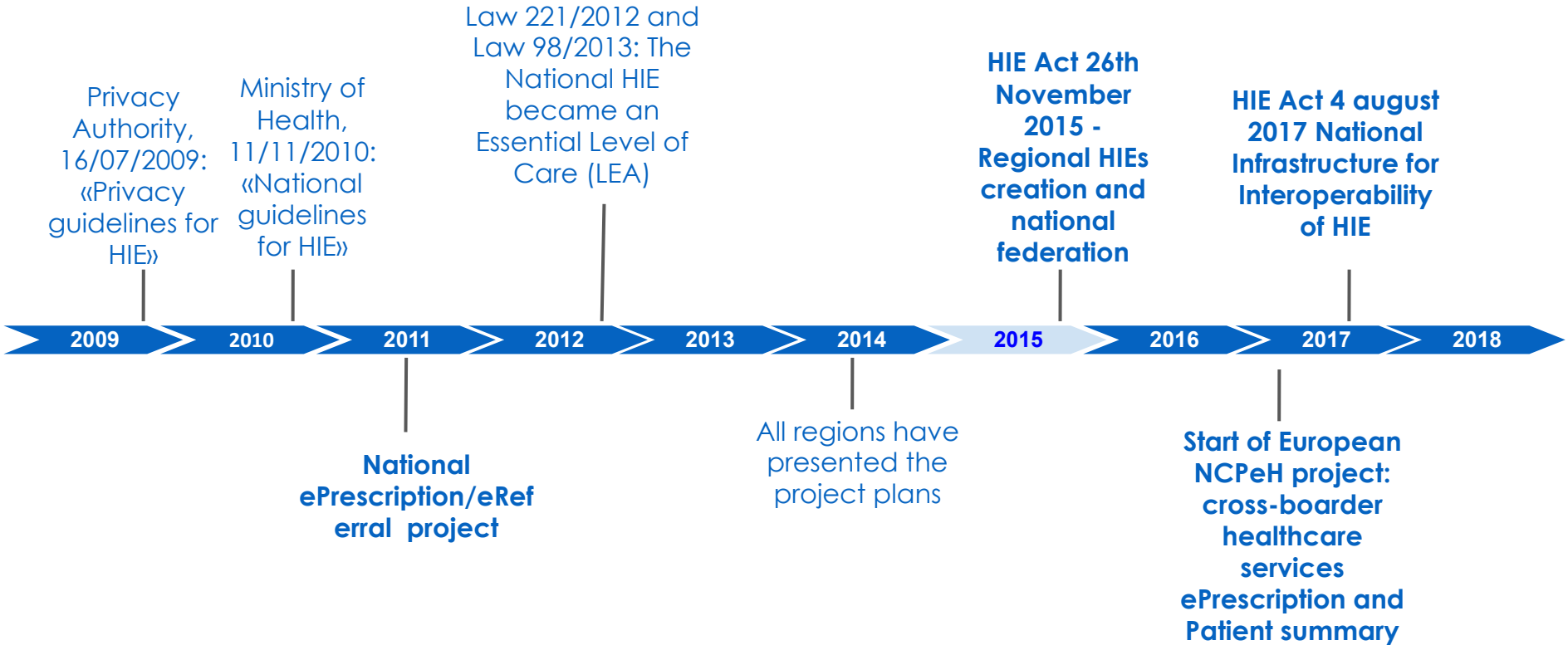
National Normative context



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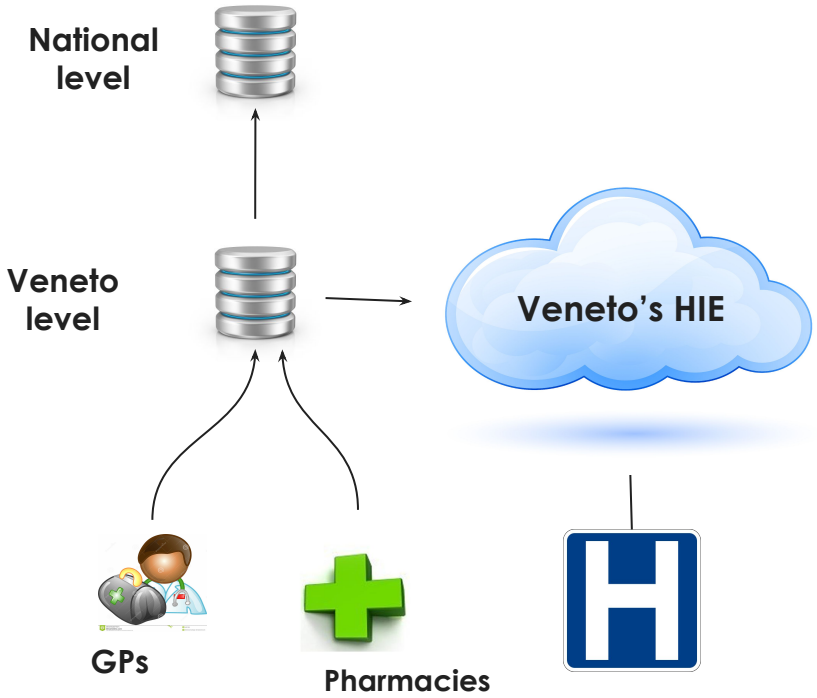
Regional Health Information Exchange (Veneto's HIE)



- ***4000*** *GP/pediatricians*
- ***1300*** *pharmacies*
- ***4,960,336*** *citizens*
- *over* ***50*** *health districts*
- ***36*** *hospitals*
- ***70.000*** *healthcare operators*

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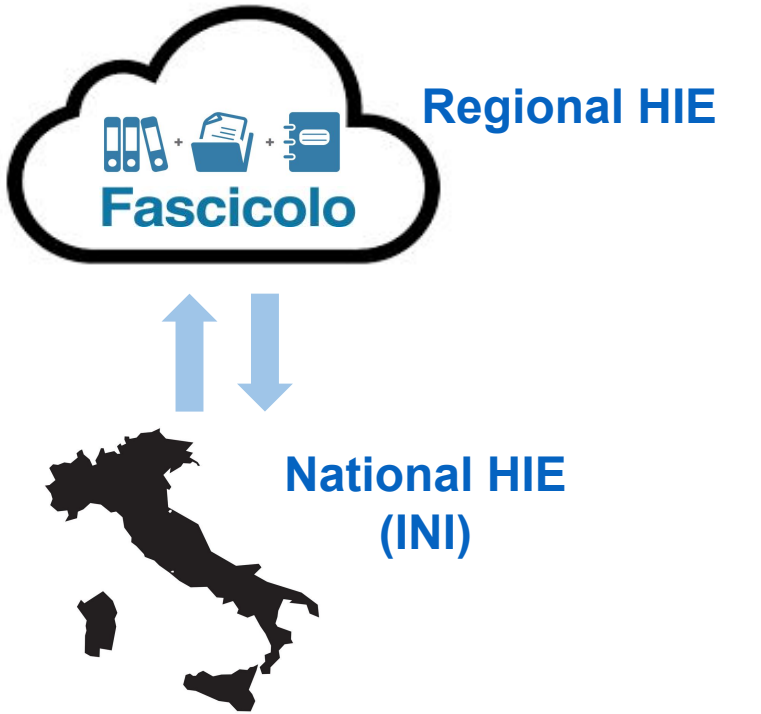
National HIE (INI)

- Manage interoperability among regional HIEs
- Support region without HIE
- Manage Patient demographic Registry
- Monitor HIE usage



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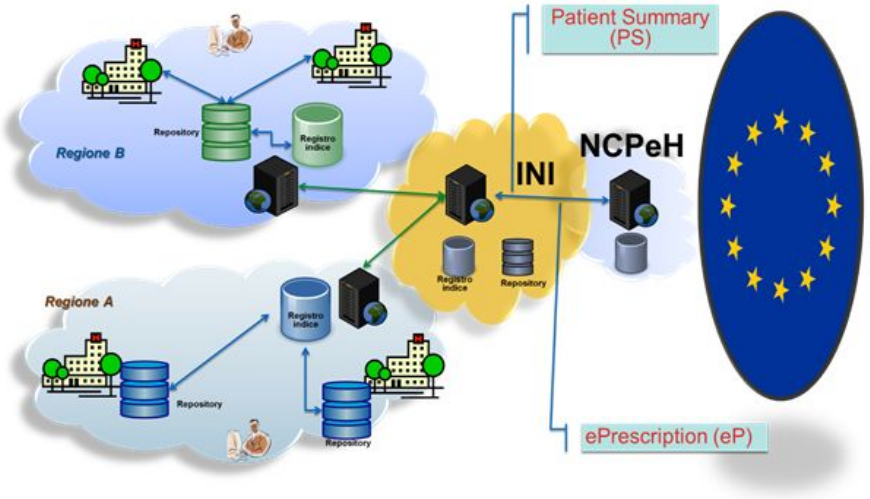
National Connector Point for EU (NCPeH)

European project for cross-boarder healthcare services in ePrescription and Patient Summary (on going)

Italian partnership:

- Ministry of Health (coordinator),
- Ministry of Economics and Finance
- AGID - technical agency of the Presidency of the Council of Ministers,
- 3 regions involved (Veneto, Lombardy, Emilia Romagna)



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Regional regulations about Testing process

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Why do we need to create a regional testing process?

- **Bad** historical **experience**: DOGE project (6 different standards born on the field)
- Increase of **complexity of integrations** and Projects
- Need to reduce **post-production issues**
- Increase the **quality of products** released
- Include **UX/UI testing**
- Grant **Security**

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Regional Normative context - Labelling

DGRV 1671 07/08/2012 Software systems that are meant to be used in the context of the project "Fascicolo Sanitario Elettronico" have to receive a certification that prove the correct implementation of the standards that have been approved by Veneto Region. Arsenàl.IT has been identified as the reference body for the development of informatic standards which are necessary for the realization of "FSEr".

The Framework Agreement (29/03/2013): **Arsenàl.IT has to provide a certification service (called "labeling")** for software systems that operate in the healthcare enterprises, to attest the right application of informatic standards approved by Veneto Region.

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Regional Normative context - Labelling

The regional note (5/09/2013, prot. 370734): Veneto Region communicated to healthcare enterprises that Arsenàl.IT would make a software platform available to systems' providers, in order to let them perform tests on their products.

DDG 11/10/2013: Arsenàl.IT produced these documents:

- The Regulations for the access and the use of the labeling service by software providers who have been authorized;
- The internal Operating Procedure about the modality to produce the labeling assessment, that certify the conformity of software systems to tecnical frameworks.

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Technical Background: HIE

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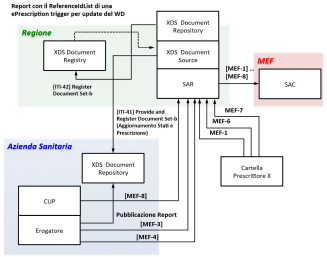
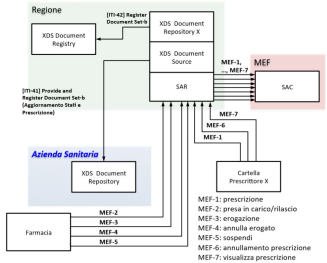
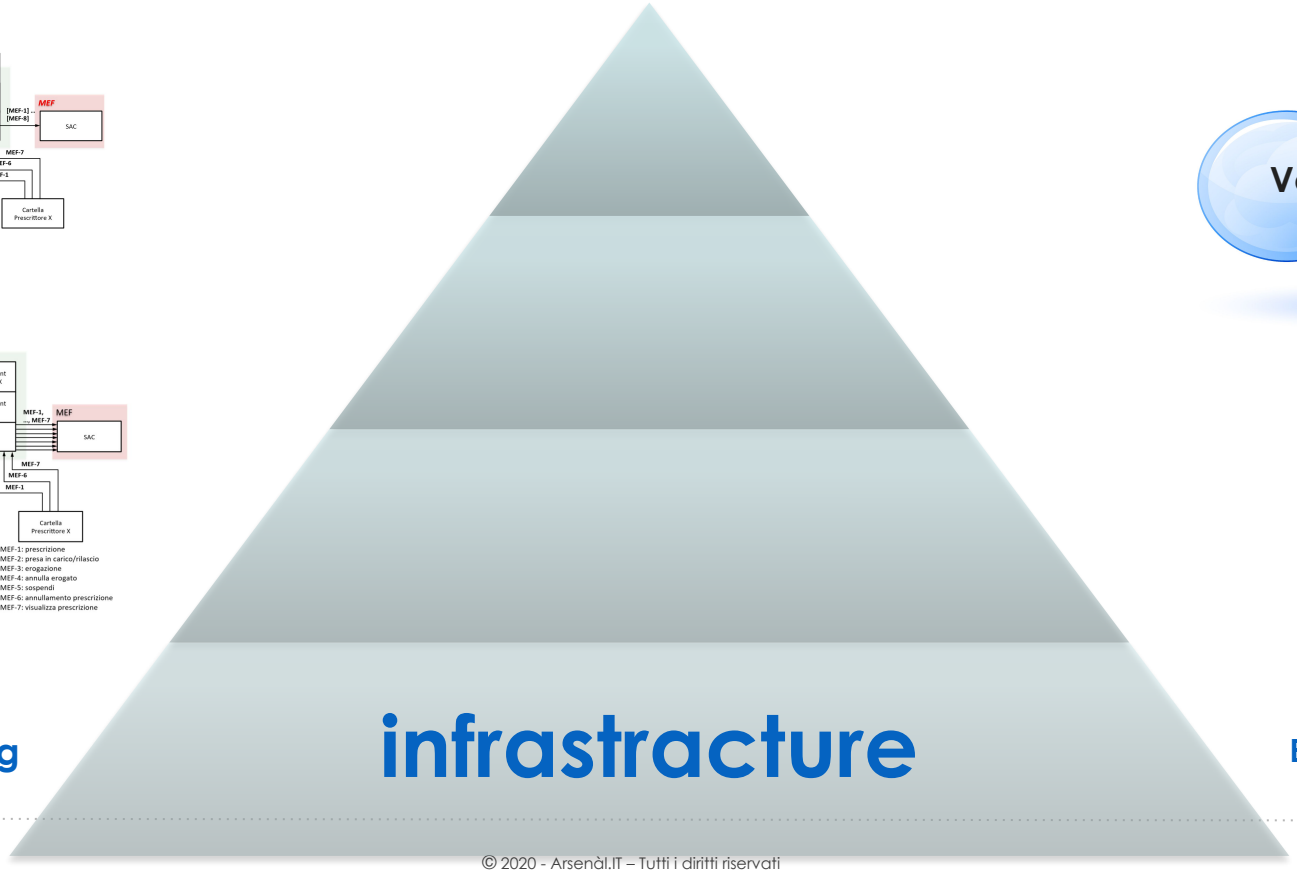
Interoperability in Veneto's HIE







Veneto's HIE

Data Sharing

infrastracture

XDS, XUA, BPPC, ATNA, CT, DSUB

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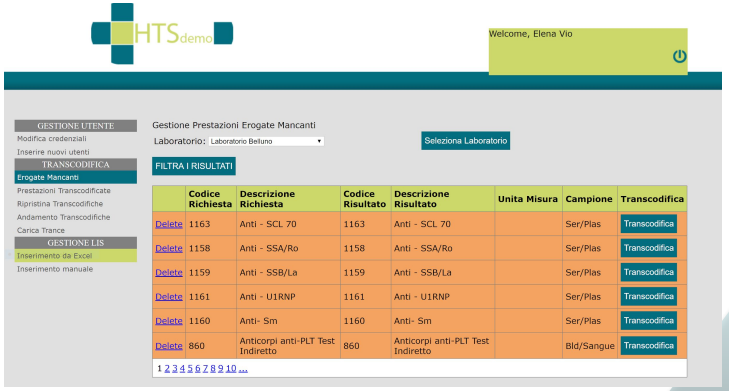
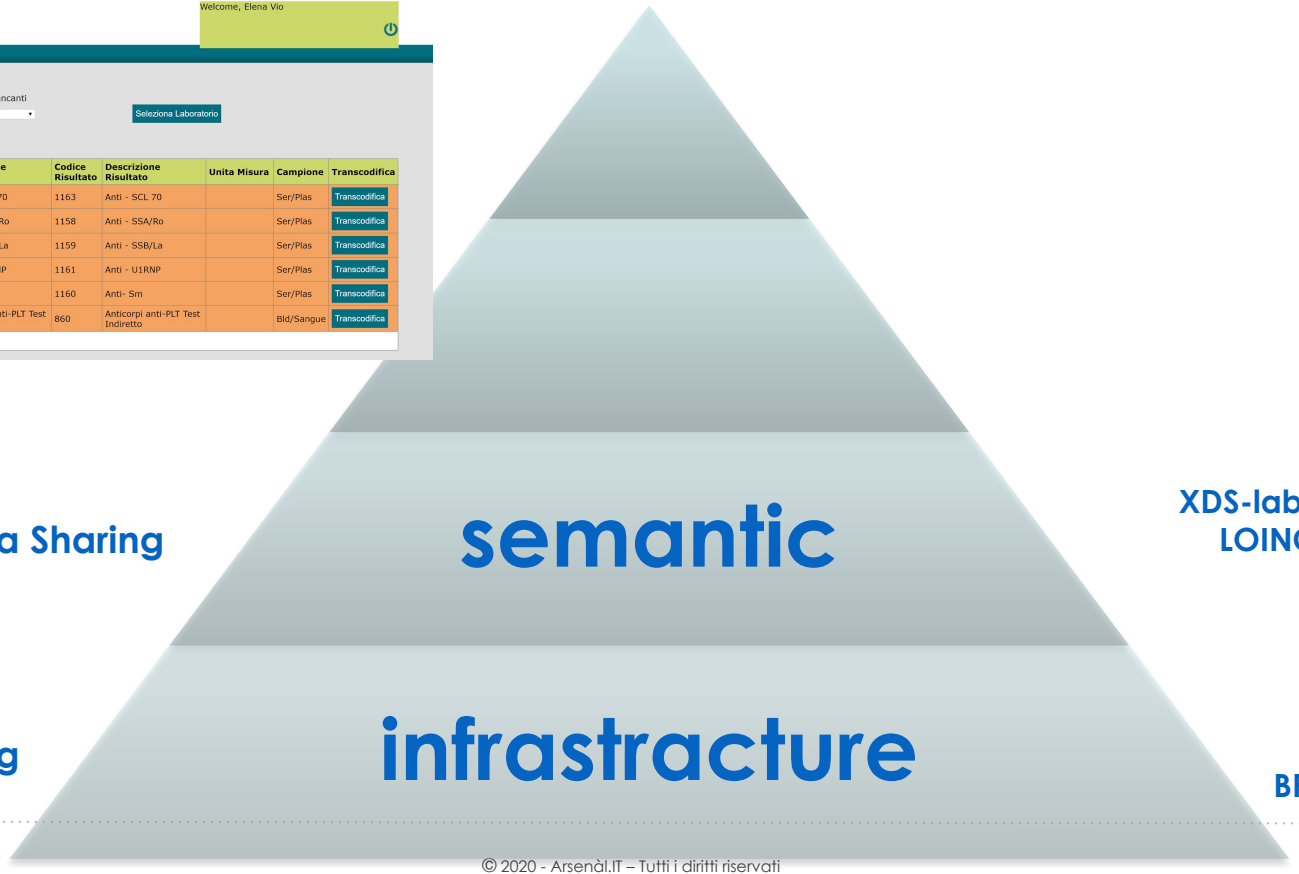
Interoperability in Veneto's HIE





Clinical Data Sharing

XDS-lab, PCC profiles LOINC mapping

Data Sharing

XDS, XUA, BPPC, ATNA, CT, DSUB

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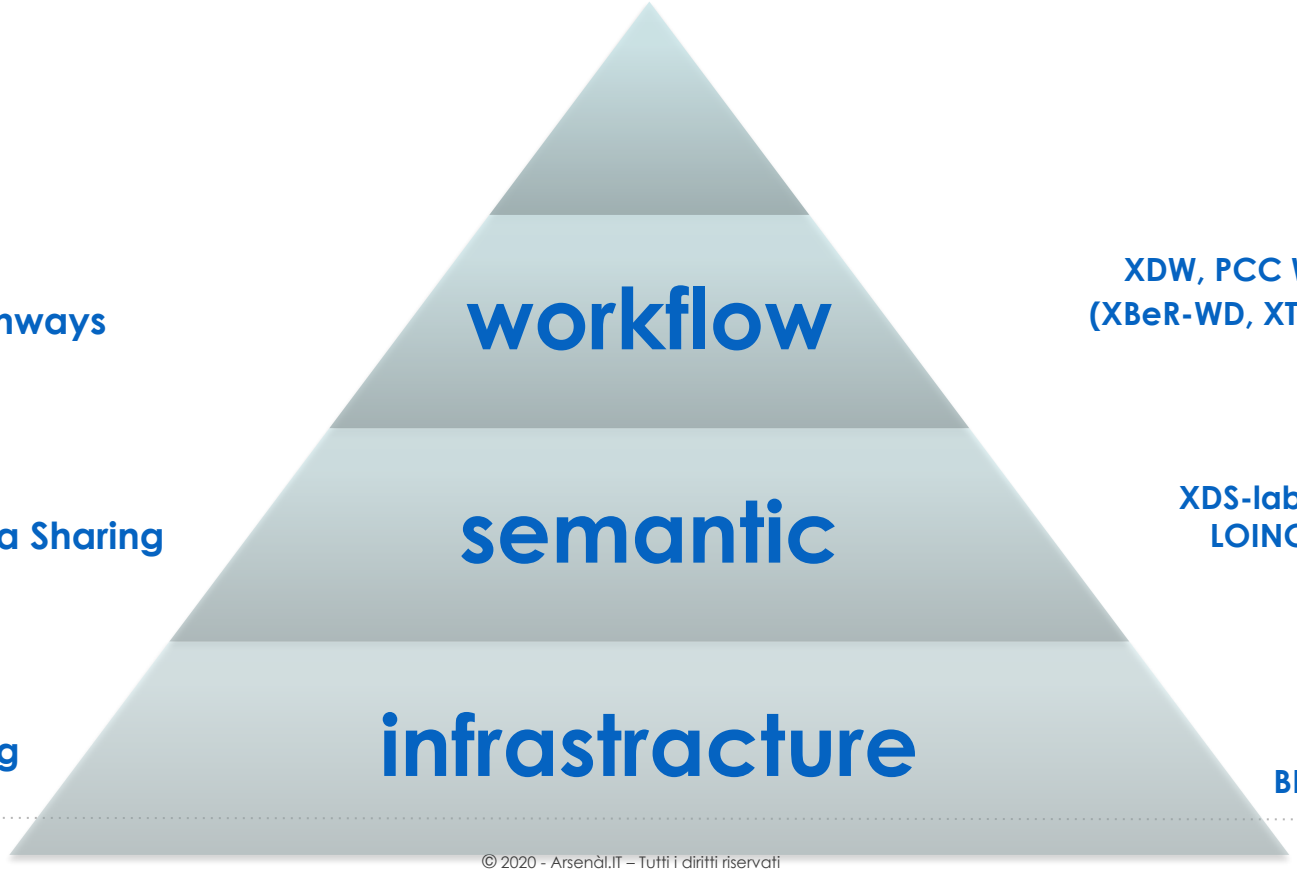
Interoperability in Veneto's HIE



Clinical Pathways

Clinical Data Sharing

Data Sharing

XDW, PCC WD profiles
(XBeR-WD, XTB-WD, etc)

XDS-lab, PCC profiles
LOINC translation

XDS, XUA,
BPPC, ATNA, CT,
DSUB

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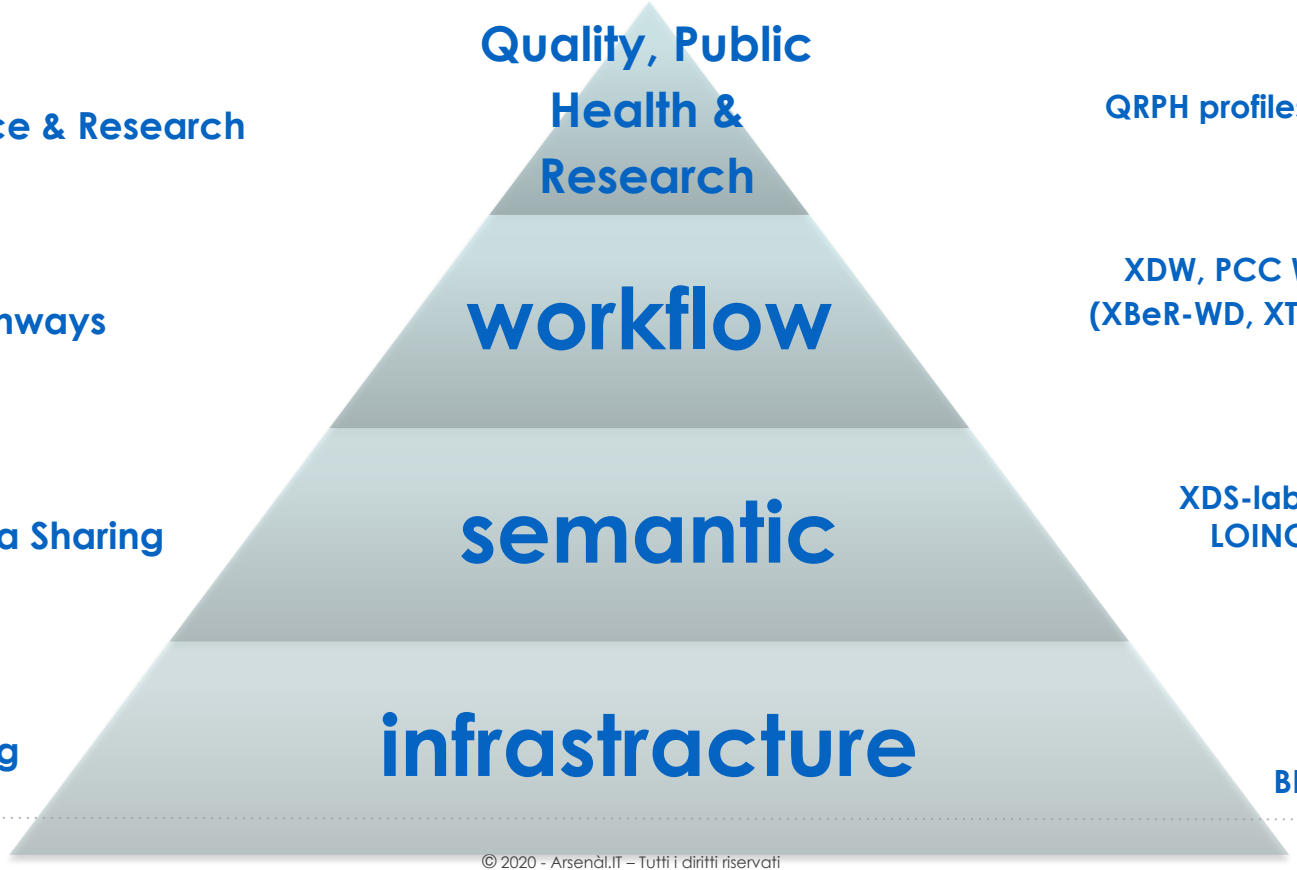
Interoperability in Veneto's HIE



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Goals of Veneto's HIE

GOALS

- to provide efficient services to **operators** and **citizens**
- to enable cross-enterprise workflow management and increase the patient engagement, starting from a common infrastructure that allows: document and data sharing, **mobile and secure access** to health data

HIE allows to easily enable new digital services, "**Sanità km zero**": new channels, new paths and new access tools to healthcare for citizens and operators **everywhere and at any time**

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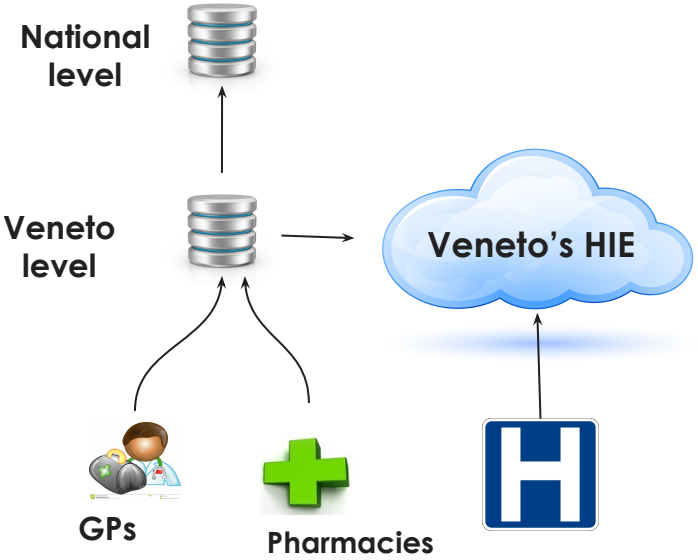
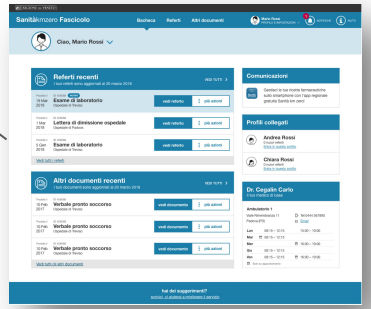
Veneto's HIE supports services for citizens



App "Sanità km zero Ricette"



Portal "Sanità km zero Fascicolo"

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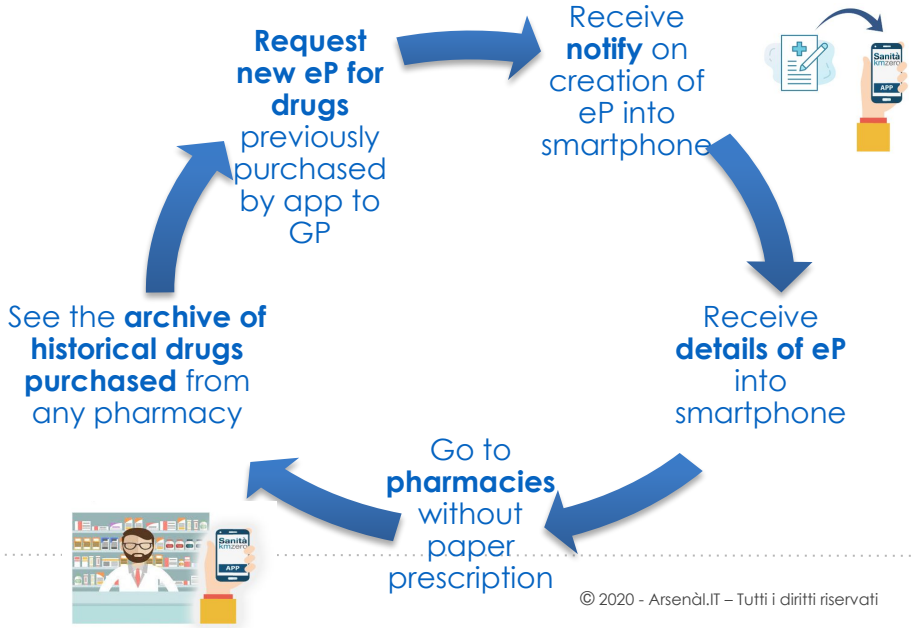
App Sanità km zero Ricette

Sanità km zero Ricette is an application mobile of **Veneto Region** that allow to manage ePrescription through smartphone thanks to **Fascicolo Sanitario Elettronico infrastructure (Veneto's HIE)**



Additional functionalities:

- acces through many channels
- manage consent
- manage ePs of patients who are minors or under legal protection

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App Sanità km zero Ricette

Benefits

- **Avoid travels and time** (3 hours/year for user) for the entire population of the Veneto Region Health System (about 5 million people in a region in Italy, thanks to:
  1) digitalization of prescription
  2) communication platform for the management of drug therapies (prescription and prescription refill)

- **Increase the empowerment** of patient

- **User friendly** application mobile, because implementation is based on co-creation approach and user centered design

- **Secure access**

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App Sanità km zero Ricette

Results

900.000
Download

220.000
Monthly access for user

3,9 in 887 feedback
Rating Apple Store

4,2 in 7733 feedback
Rating Google Play

Request of new ePrescription to GP in 90 days: 123.760

MAIL	WHATSAPP	SMS	TEL. (F + M)
74.500	21.800	15.500	11.960

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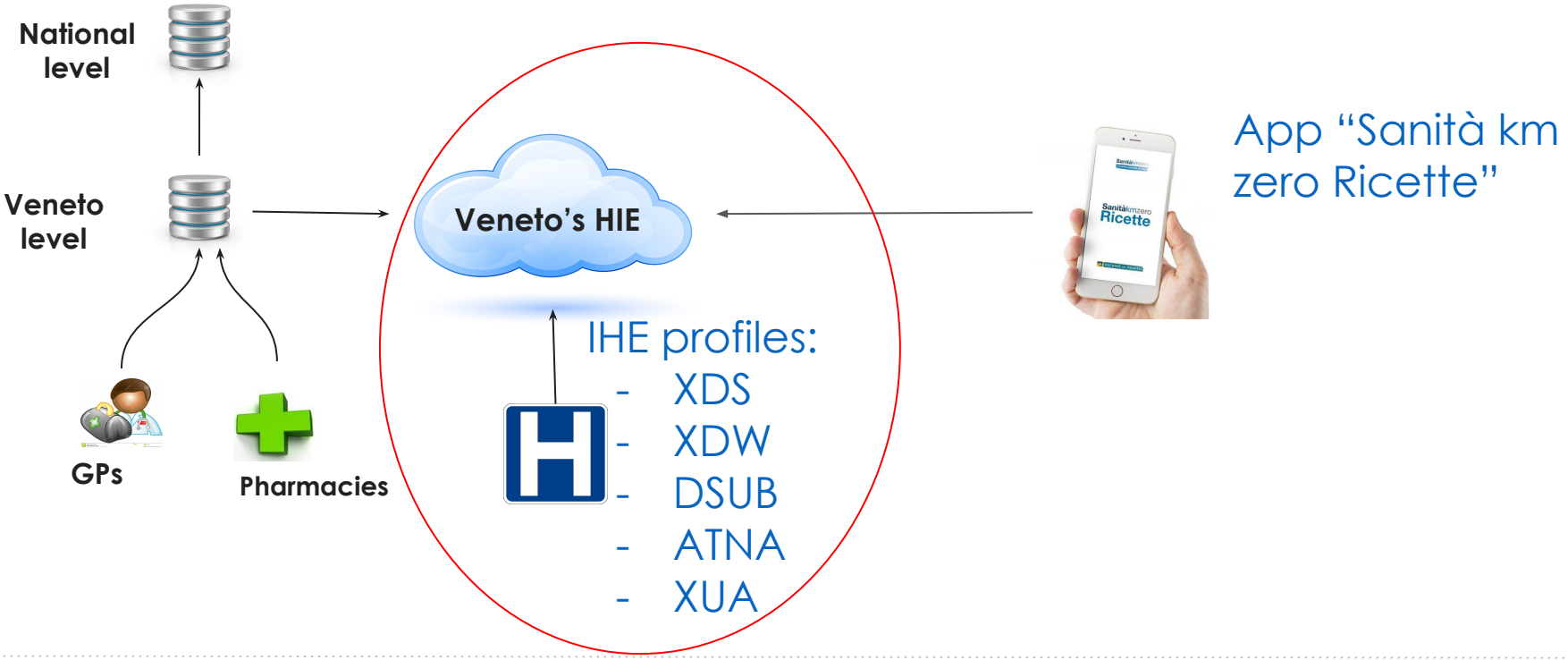
Integration of app Sanità km zero to Veneto's HIE

Approach



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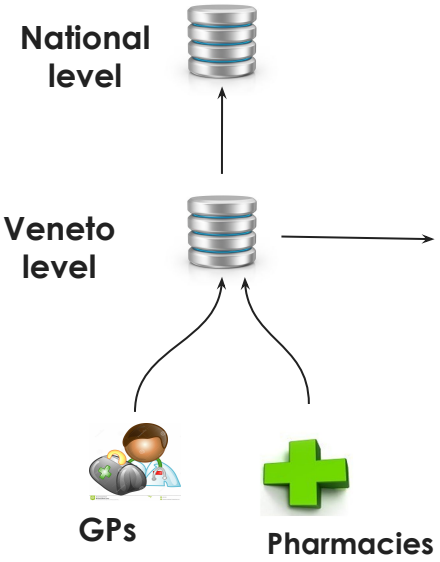
Integration of app Sanità km zero to Veneto's HIE

Approach



IHE profiles:

- XDS
- XDW
- DSUB
- ATNA
- XUA

App "Sanità km zero Ricette"

IHE profiles based on **REST**:

- MHD
- PDQm
- IUA

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Application of IHE profiles

IHE Profiles based on FHIR® standard that are relevant in the mHealth field, because are based on the Representational State Transfer (REST) and **RESTful architectural style**:

- **MHD** (Mobile access to Health Documents): profile applied in order to obtain clinical documents (ePrecriptions, eDispendations, and Consents)
- **PDQm** (Patient Demographics Query for Mobile): profile applied in order to obtain patient demographic or information about GP
- **IUA** (Internet User Authorization) profile applied in order to manage the secure access

Easy for implementation
Suitable for lightweight devices
Solution as **reusable** as possible for other services

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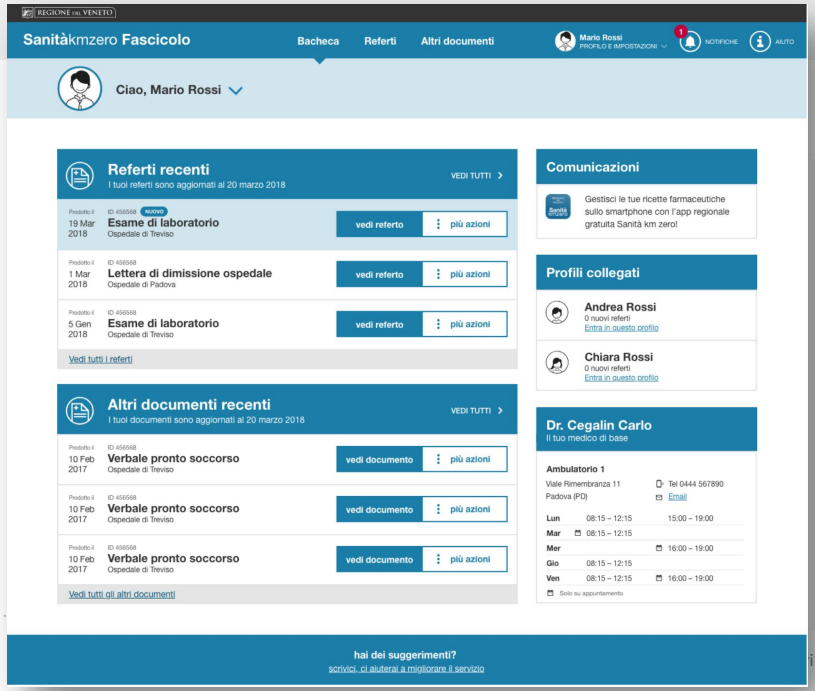
Portal “Sanità km zero Fascicolo”

Sanità km zero Fascicolo is a portal that allow to see clinical documents of the citizen thanks to **Fascicolo Sanitario Elettronico infrastructure (Veneto’s HIE)**



Functionalities:

- secure access through many channels
- see clinical documents
- obscure documents
- manage notifications
- manage consent
- manage docs of patients who are minors or under legal protection

Testing & Tools: strategy and roles

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Which Tools?

Test platform:

- Gazelle Test Management
  - Pre-Test (performed remotely)
  - Test in real time (performed in our headquarter)
- EVSclient
  - It allows to apply: SCHEMA validation and SCHEMATRON validation
  - we are producing our own schematrons
- SchematronValidator
- Gazelle Proxy
  - Monitor messages + Linked to EVS Client

Some additional tools:

- Mock Services / Simulators (MIRTH integrator , PHP , SOAP UI)
  - Load Testing
  - Functional Testing (to HTTP protocol issues…)
  - WSDL Validation
  - Mock services
  - Schematron engine
  - Integration of other services
  - More complex BI of the simulator
- PHP Toolkit

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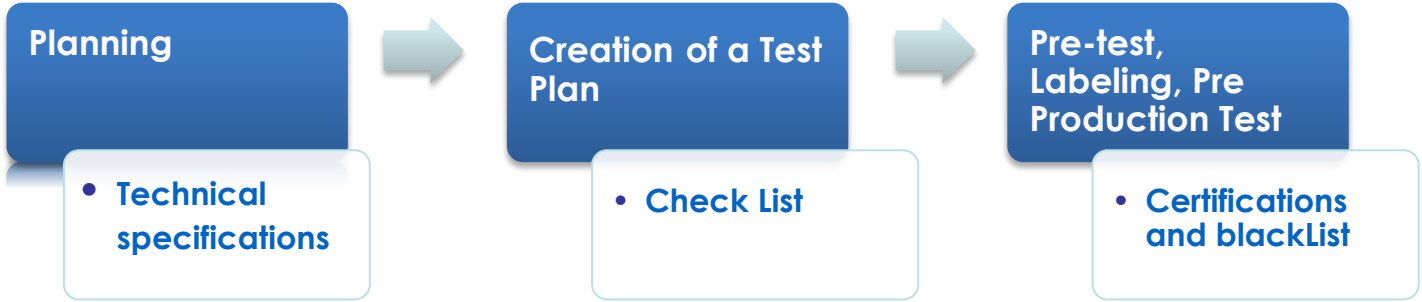
Testing Process

Labeling in HIE project:

Process that produces for a software system a certification that allow it to operate in the HIE infrastructure.

The process:



Test Types:

Pre-Test

- no peer
- peer-to-simulator
- peer-to-peer

Labeling

- no peer
- peer-to-simulator
- peer-to-peer

Pre-Production Test

- scenario
- peer-to-peer

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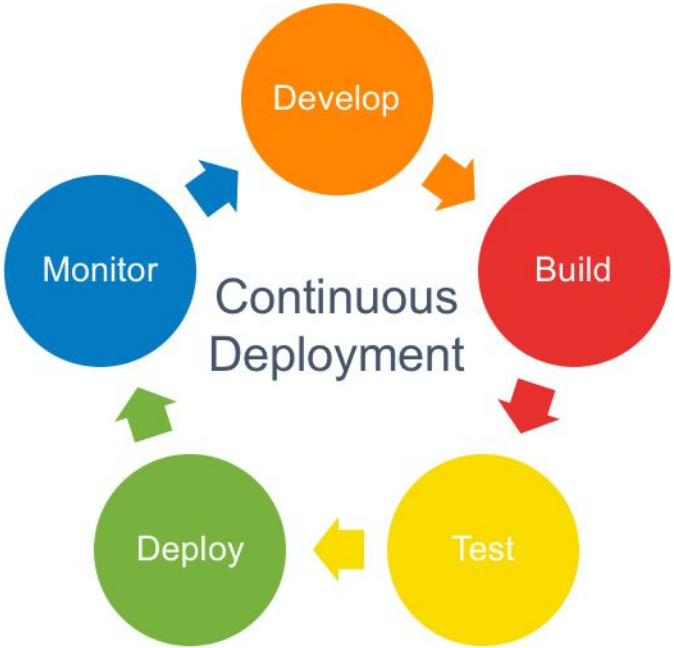
Post-production testing

- Scope:
  - Time-to-fix reduction
  - Facilitation of the introduction of Continuos-Deployment processes
  - Application of a scoring on the organization that produces the artifacts
  - Prevention of clinical risks related to incorrect interpretation of artefacts
  - Raising of quality of the data



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Procurement Support

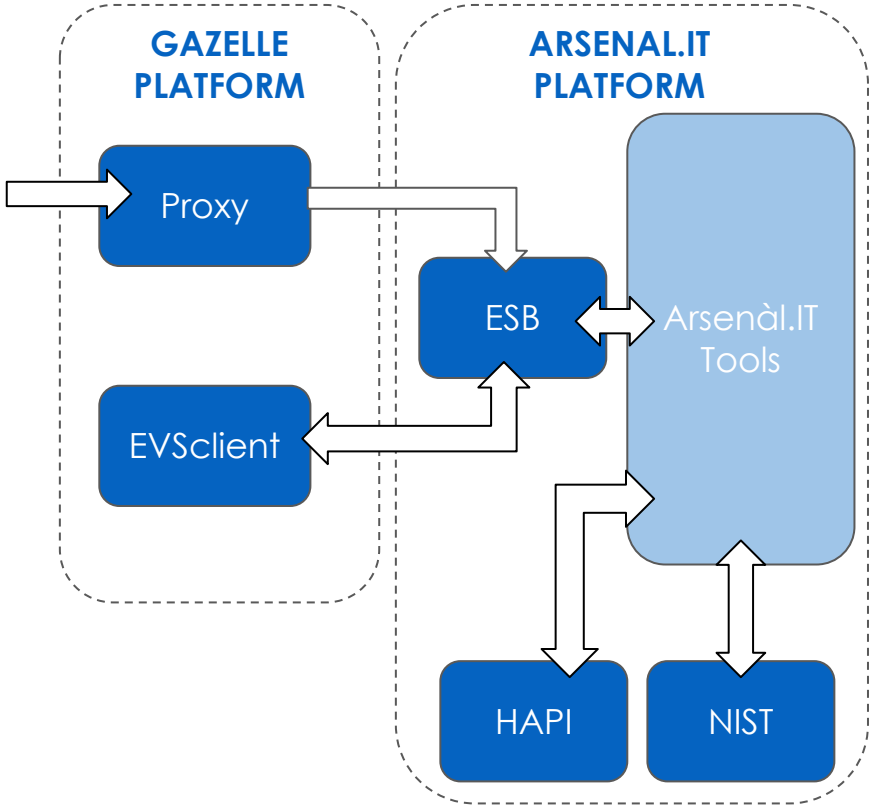
Arsenàl.IT provided testing support in order to evaluate different systems:

UX/UI Testing: using standardized questionnaire (SuS , Nielsen)

Interoperability testing: using standardized tools orchestrated by an Arsenàl.IT tool

- Gazelle Test Management: collect evidence
- EVSclient: live SCHEMA validation and SCHEMATRON validation
- Gazelle Proxy: Monitor messages + Linked to EVS Client
- NIST: standard WS SOAP
- HAPI: standard FHIR HL7 API

Performance testing: using well-known open-source tools.



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Thank you!

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