The value of Real World Evidence in Clinical Trials

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REAL WORLD EVIDENCE & DIGITAL HEALTHCARE

Why it matters

- Develop **data-driven hypotheses** for research and support to clinical practice
- Optimize costs and performance of clinical trial by **integrating** evidence from **observational studies**

Focus areas

Standard framework for: architecture, process, roles & responsibilities)

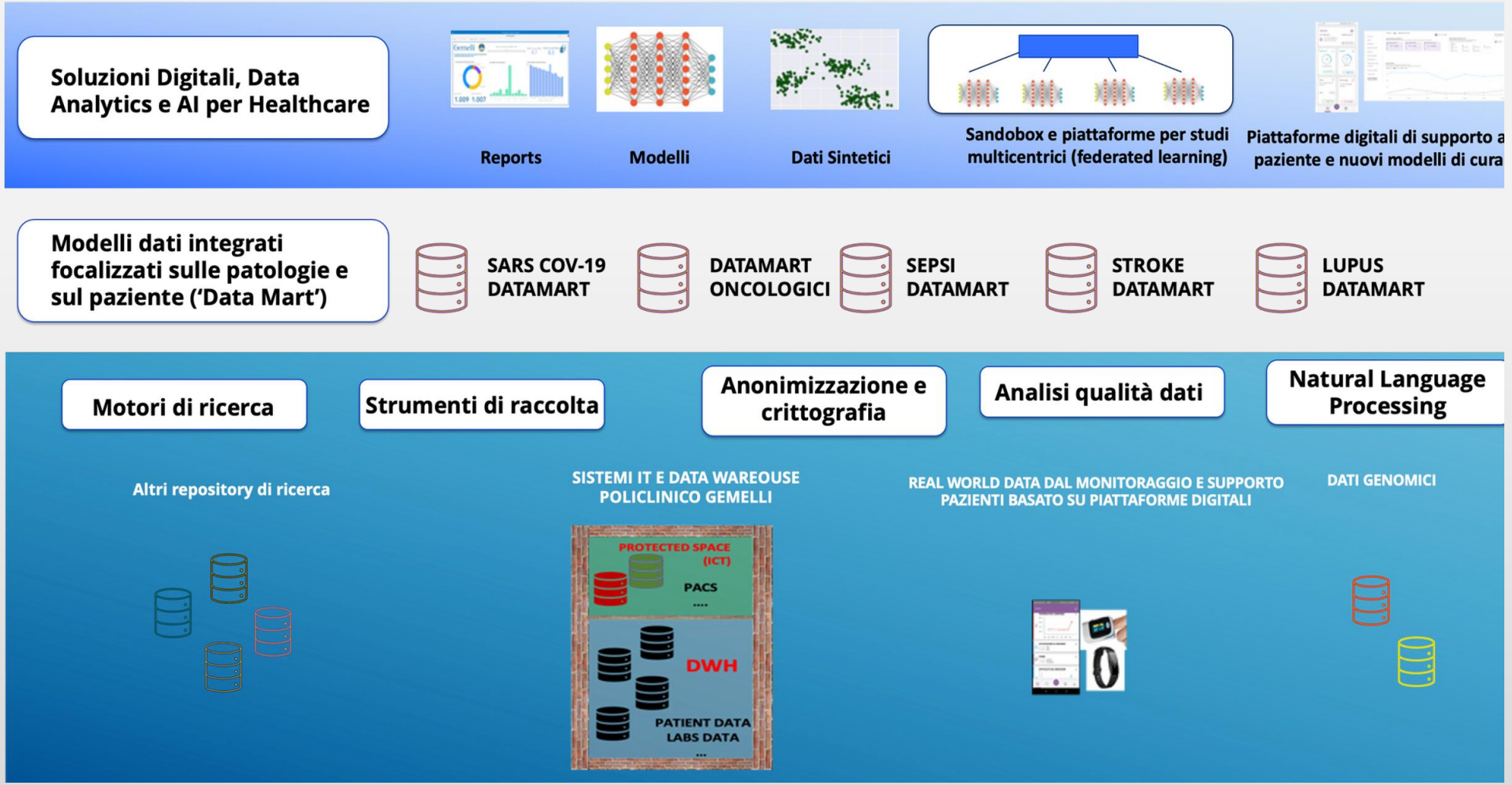
Compliance to **privacy & ethical standard**

Data **Quality** and Process **Traceability**

Co-design with industry & research

GEMELLI GENERATOR REAL WORLD DATA RESEARCH FACILITY

Leverage **Real World Evidence and Data Science** techniques to enable new insights in clinical research and practice



GENERATOR RWE INFRASTRUCTURE

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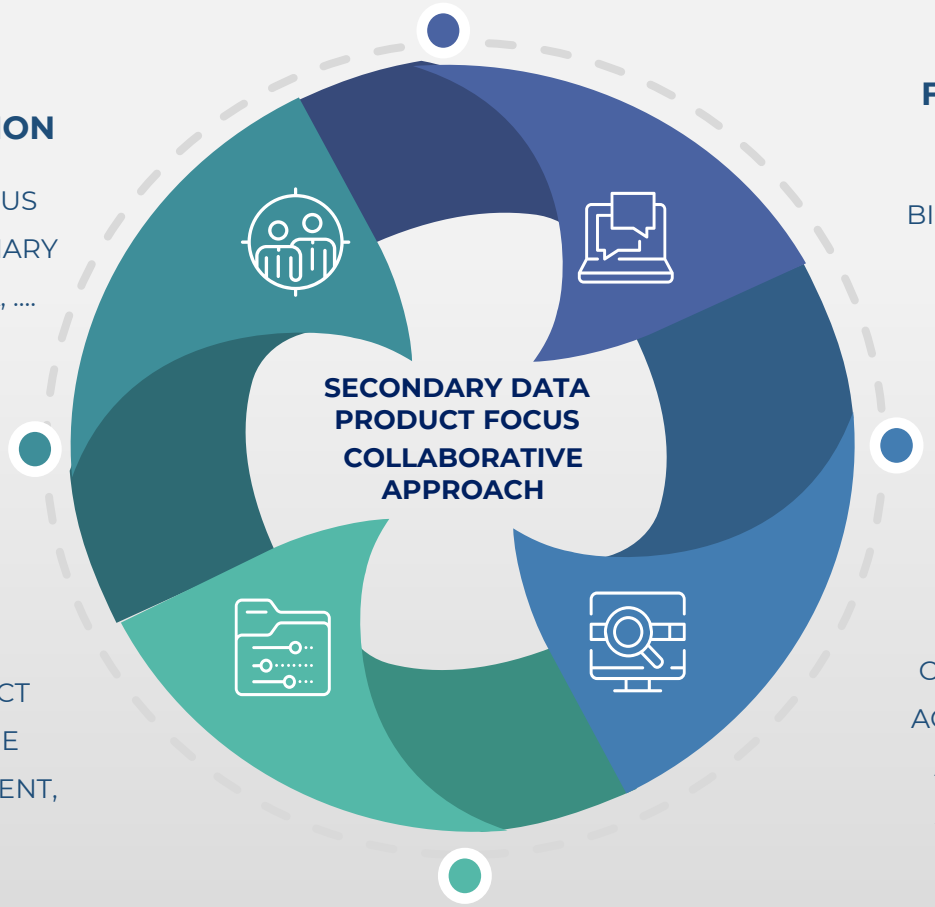
GEMELLI DIGITAL MEDICINE & HEALTH
GEMELLI NewCo for Digital Healthcare

Mission: exploit the full potential of **knowledge-base of Gemelli** within Digital Health landscape and develop **RWE / digital medicine solutions** with full ethical, technical and regulatory credentials.



PRELIMINARY RESEARCH QUESTION

DISEASE AREAS, FOCUS AND GOALS, PRELIMINARY INCLUSION CRITERIA, ...

FEASIBILITY ANALYSIS

VOLUMES, OUTCOMES, BIOMARKERS, BUDGETING AND TIMELINE DISCUSSION

CONTRACTING

FINALIZATION OF PROJECT DELIVERABLES, TIMELINE ECONOMICS, IP MANAGEMENT, GENERAL T&CS

ETHICS AND DATA

COMPLIANCE VALIDATION ACCORDINGLY WITH GDPR, AGREEMENT ON MEANS AND GOALS, PROTOCOL PREPARATION

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HOW TO UNLOCK RWD VALUE

Challenges

- ❑ A vast amount of data
- ❑ Data heterogeneity
- ❑ Data silos
- ❑ Data privacy
- ❑ Know-how

What is needed

- ➢ An adequate data management system
- ➢ Data quality solutions
- ➢ Analytical techniques to handle sensitive data
- ➢ Advanced analytics
- ➢ High-computing performance
- ➢ Open source integration

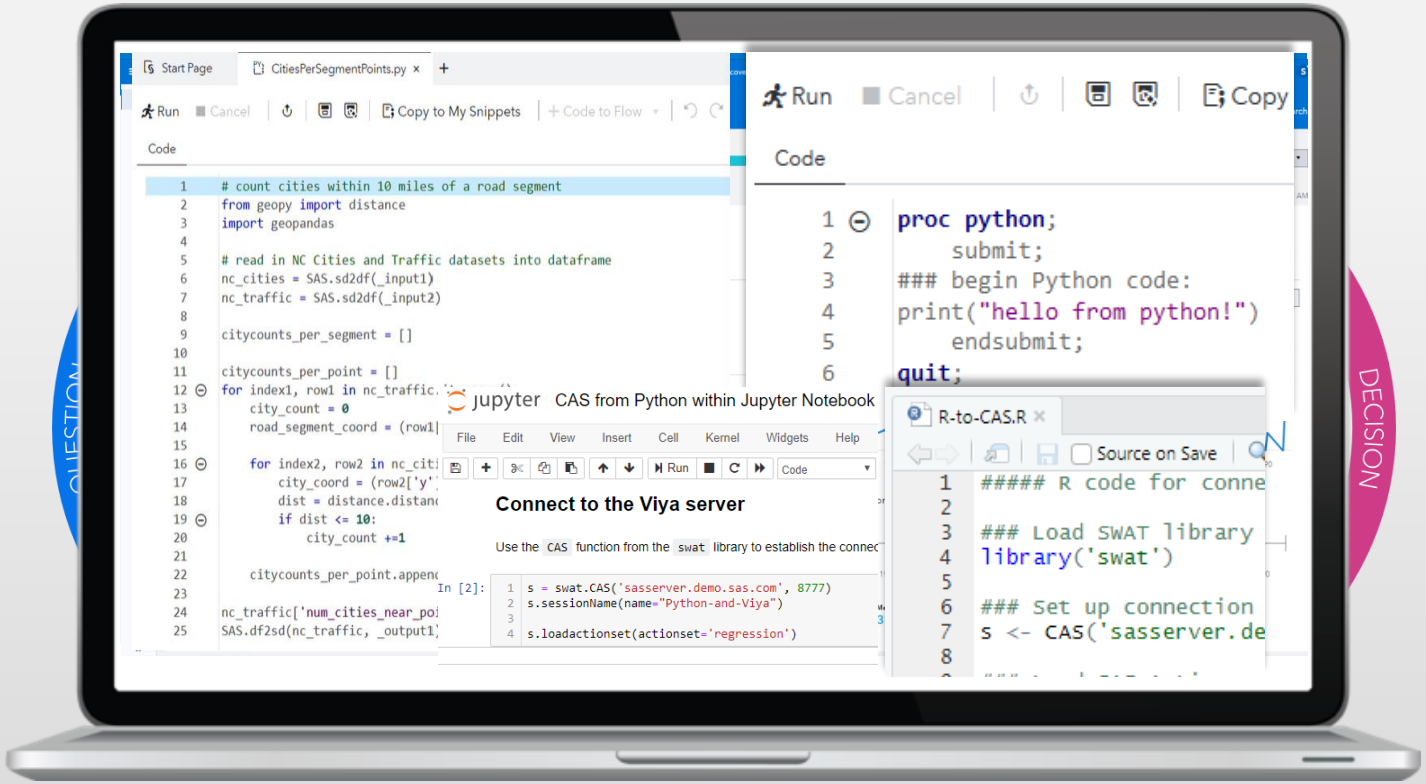
THE IMPORTANCE OF HAVING AN ALL-IN-ONE SOLUTION

HOW SAS DELIVERS

Improve efficiency

Increase collaboration

Effectively manage RWD & Analytics Assets



Principal Investigator: Dr. A. Orlandi

USE CASE: DESIGN OF CLINICAL TRIAL

FOCUS: patient identification and selection criteria

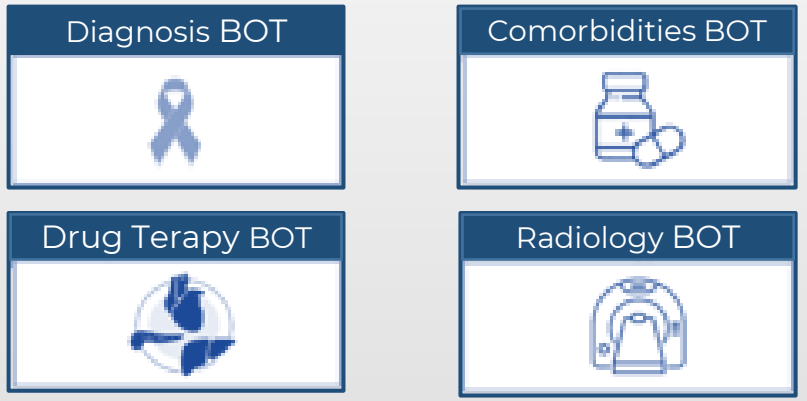
Step 1: automated procedures to filter patients on first-level inclusion / exclusion criteria

Step 2: AI-based rules for composite clinical parameters (example: subtype)

Step 3: provide clinical research team with actionable information

TECHNICAL SOLUTION

- Specialized AI engines ("SEARCH" BOTs) that automatically crawl into the different domains of Breast DATA MART



- Natural language understanding on free text medical reports + rule engines co-designed with clinical team
- User-oriented data visualization and drill-down tools to analyze patient history in depth

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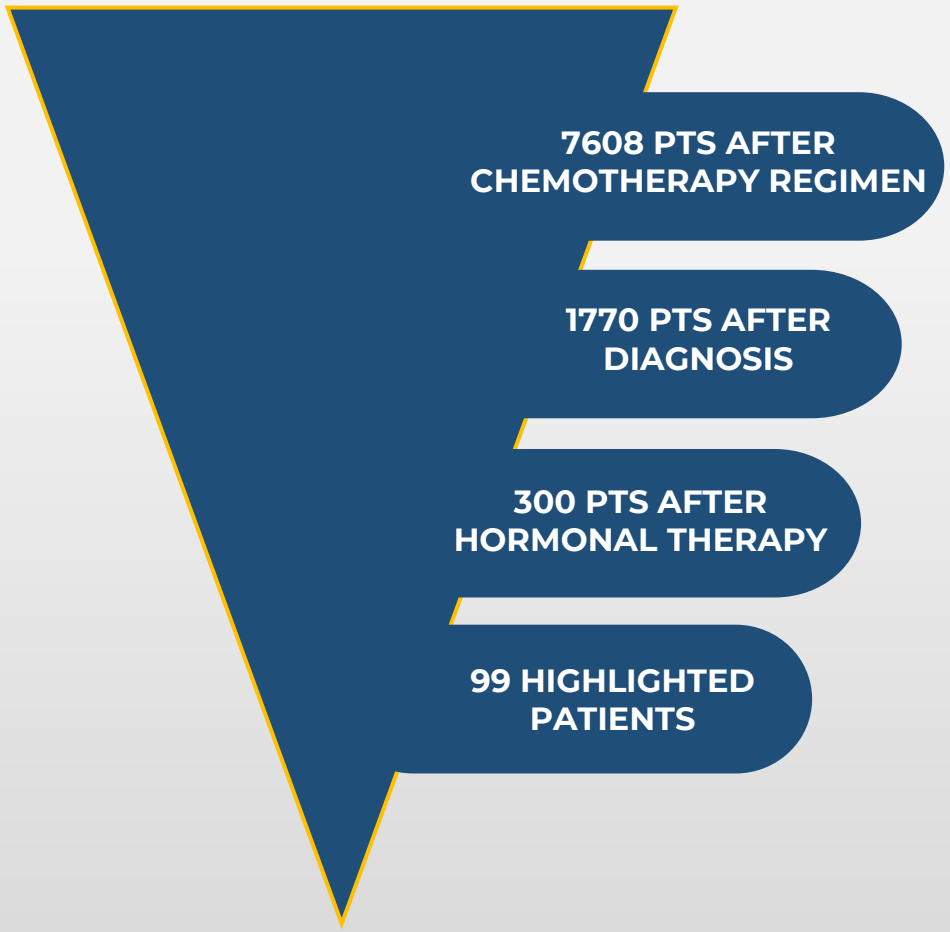
USE CASE: DESIGN OF CLINICAL TRIAL

FOCUS: patient identification and selection criteria

USE CASE

Key Inclusion/Exclusion Criteria

- History og low HER2 expression
- Refactory endocrine therapy (HR+HR – Cohort)
- Has been treated with al least 1 or most 2 prior lines of chemoterapy in current or metastatic setting
- Never previously treated with anti-HER2 therapy (never previously HER2-positive)
- Presence of at least 1 measurable lesion according to m RECIST v1.1
- No historyof myocardial infection in the last 6 month
- No history of interstitial lung disease
- No clinically active central nervous system metastases



Recruitment timeline **2 years / 1 patient selected**

Screening based on AI-tool: **4 weeks**

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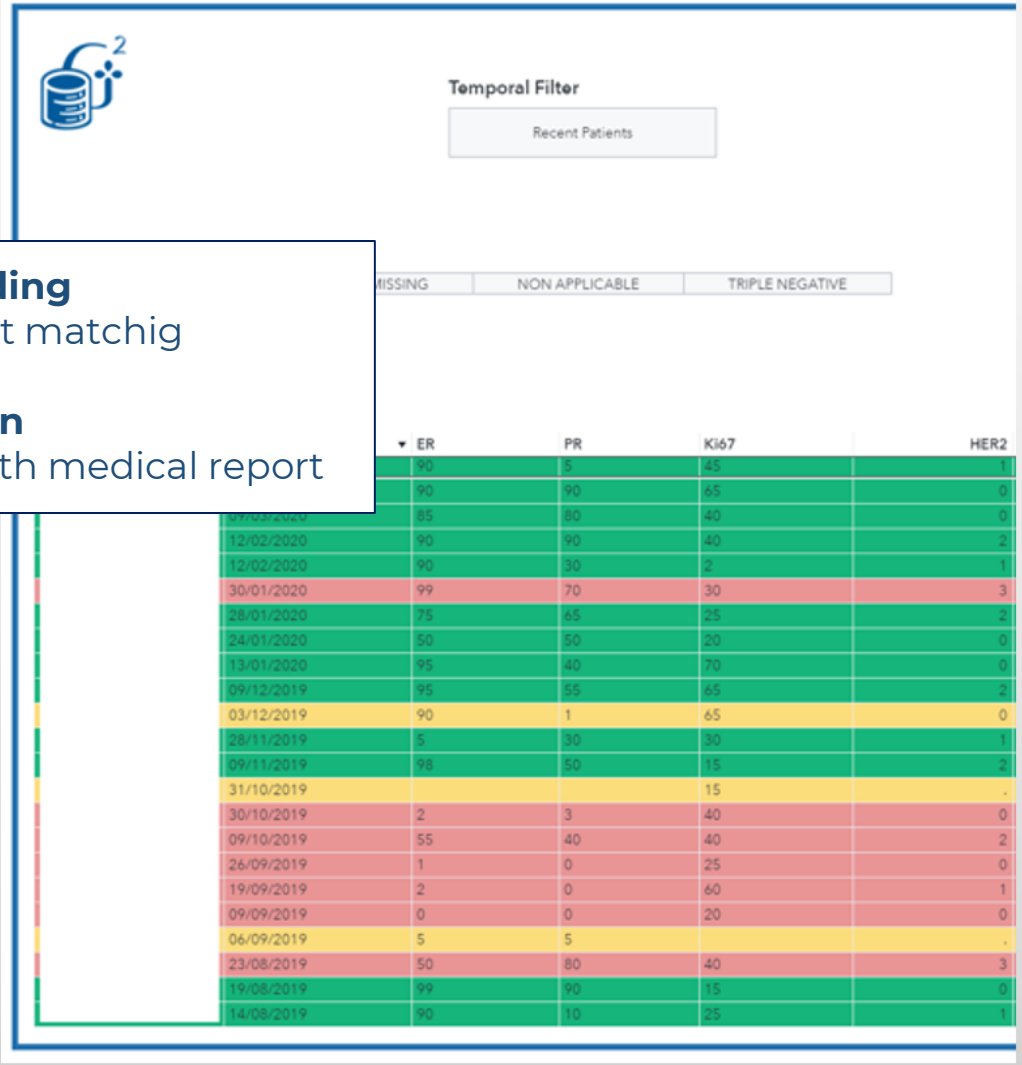
USE CASE: DESIGN OF CLINICAL TRIAL

FOCUS: patient identification and selection criteria

Color-coding
- Patient matchig

Drill-down
- In depth medical report



ER	PR	Ki67	HER2
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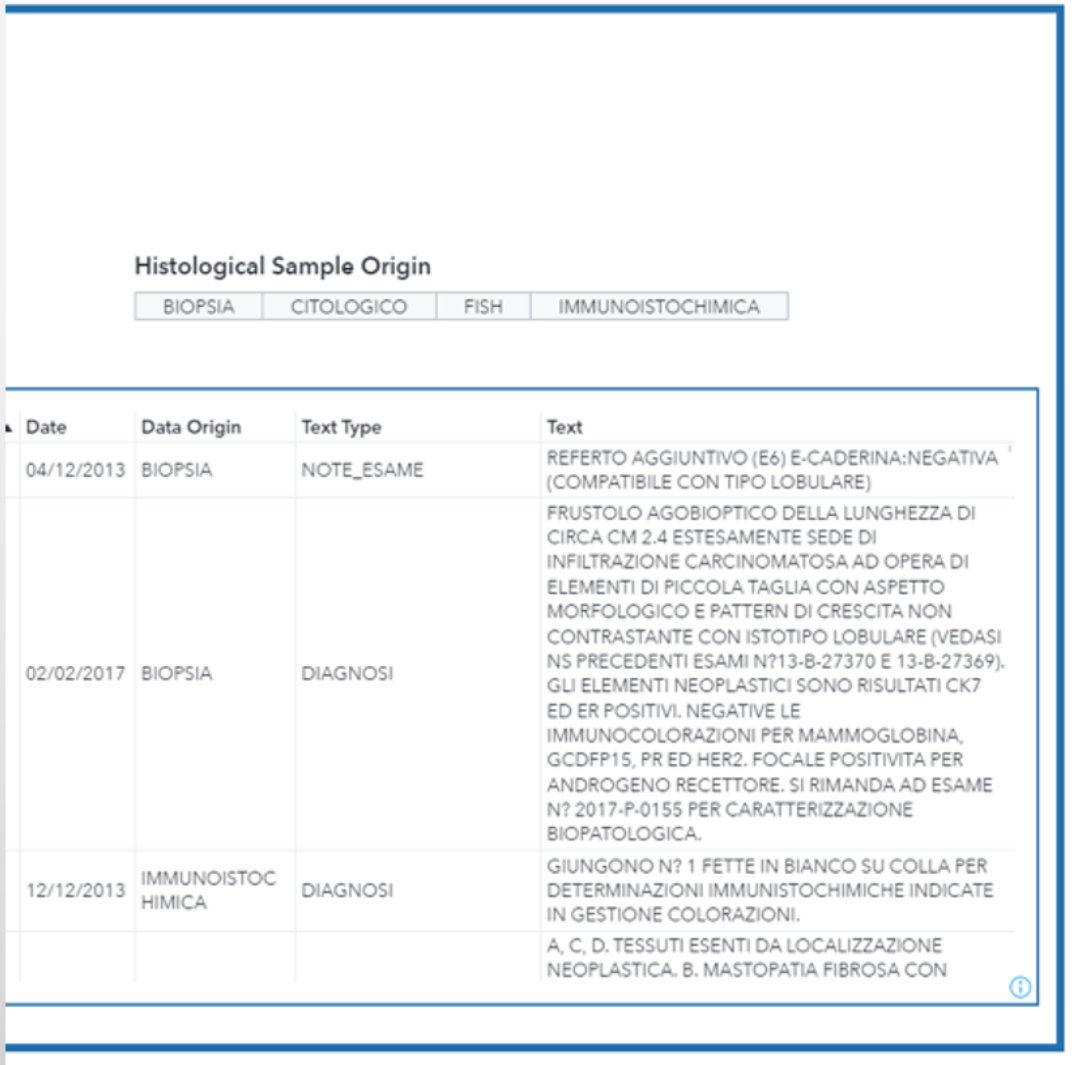
90	90	65	0
85	80	40	0
90	90	40	2
90	30	2	1
99	70	30	3
75	65	25	2
50	50	20	0
95	40	70	0
95	55	65	2
90	1	65	0
5	30	30	1
98	50	15	2
		15	.
2	3	40	0
55	40	40	2
1	0	25	0
2	0	60	1
0	0	20	0
5	5		.
50	80	40	3
99	90	15	0
90	10	25	1



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			A, C, D. TESSUTI ESENTI DA LOCALIZZAZIONE NEOPLASTICA. B. MASTOPATIA FIBROSA CON

KEY TAKEAWAYS / DISCUSSION POINTS

- Systemic approach to RWE generation is gaining traction and expanded use
- Cross-competence teams and agile methods are critical success factors
- Co-design clinical research / industry / tech partners