The value of Real World Evidence in Clinical Trials

S. Patarnello
Gemelli Generator Real World Data
Gemelli Digital Medicine & Health

Marta Cicchetti
Advanced Analytics & AI team, SAS

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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
Leverage Real World Evidence and Data Science techniques to enable new insights in clinical research and practice.
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.
### 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
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
  - Diagnosis BOT
  - Comorbidities BOT
  - Drug Terapy BOT
  - Radiology BOT

- 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
**USE CASE: DESIGN OF CLINICAL TRIAL**

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**USE CASE**

Key Inclusion/Exclusion Criteria

- History of low HER2 expression
- Refractory endocrine therapy (HR+HR – Cohort)
- Has been treated with at least 1 or most 2 prior lines of chemotherapy 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 history of myocardial infection in the last 6 months
- 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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Color-coding
- Patient matching

Drill-down
- In depth medical report
• 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