

Development of New Therapies and Clinical Trials in Lombardy Region How to Close the Gap? Expert Round Table

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Clinical reserach: a change in perspective

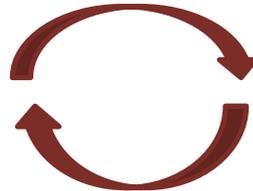
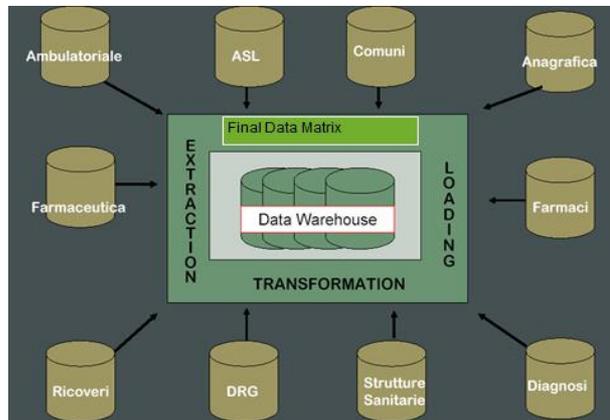


The opportunity for value added real-world research

Lombardy Health Service Databases

Since 1997, an automated system for linking healthcare utilization databases is in place (10 mil inhabitants, 16% of the whole Italian population)

Medical records databases (e.g. ULNet GP network, HealthSearch, Pedianet) and population-based disease registries (e.g. cancer registries, WHO-MONICA) are also available



Lombardy is particularly attractive for conducting **real-world studies** on real-world data

Within the **appropriate methodological framework**, real-world research on **secondary (existing) data** can provide **scientific evidence** on health outcomes and healthcare interventions, relevant to decisions made by clinicians and all stakeholders who participate in health care, that can significantly improve the cure and care of patients

The opportunity for value-added real world research

New challenges, new proposals

Real-world data add to the RCT evidence base by providing:

- **Assessment of effectiveness in a real-world setting**
- **Comparative evidence against multiple realistic comparators**
- **Improved understanding of benefit–risk profile**
- **Broader range of real-world outcomes than those measured in RCTs**

Need to revise current existing operational framework

Linea Guida AIFA per la classificazione e conduzione di studi osservazionali sul farmaco (G.U. 76 del 31 Marzo **2008**) ONLY applicable to observational prospective studies on drugs

Need to build competencies for review / approval of observational retrospective protocols and properly norm data access/utilization, data property, data publication (Ethical Committees? Comitato Regionale di Valutazione?)

The opportunity for value-added real world research

New challenges, new proposals

The recent Delibera Regione Lombardia (July 2014) represent a major step forward to regulate access to Lombardy datawarehouse. But key stakeholders are missing.....

Industry

Need real-world data on effectiveness, safety, PROs, costs to support the value of drugs/devices

Real-world evidence guide future R&D investments

Qualified research bodies

Secure the proper methodological analyses for interpretation of real-world data

Region

Need real-world data on relation between interventions-outcomes-sustainability for planning, management and control

Physicians and Scientific Societies

Need real-world data on effectiveness, safety and PROs to make decisions for patients and inform guidelines

