Linee guida e responsabilità mediche: cosa deve cambiare?

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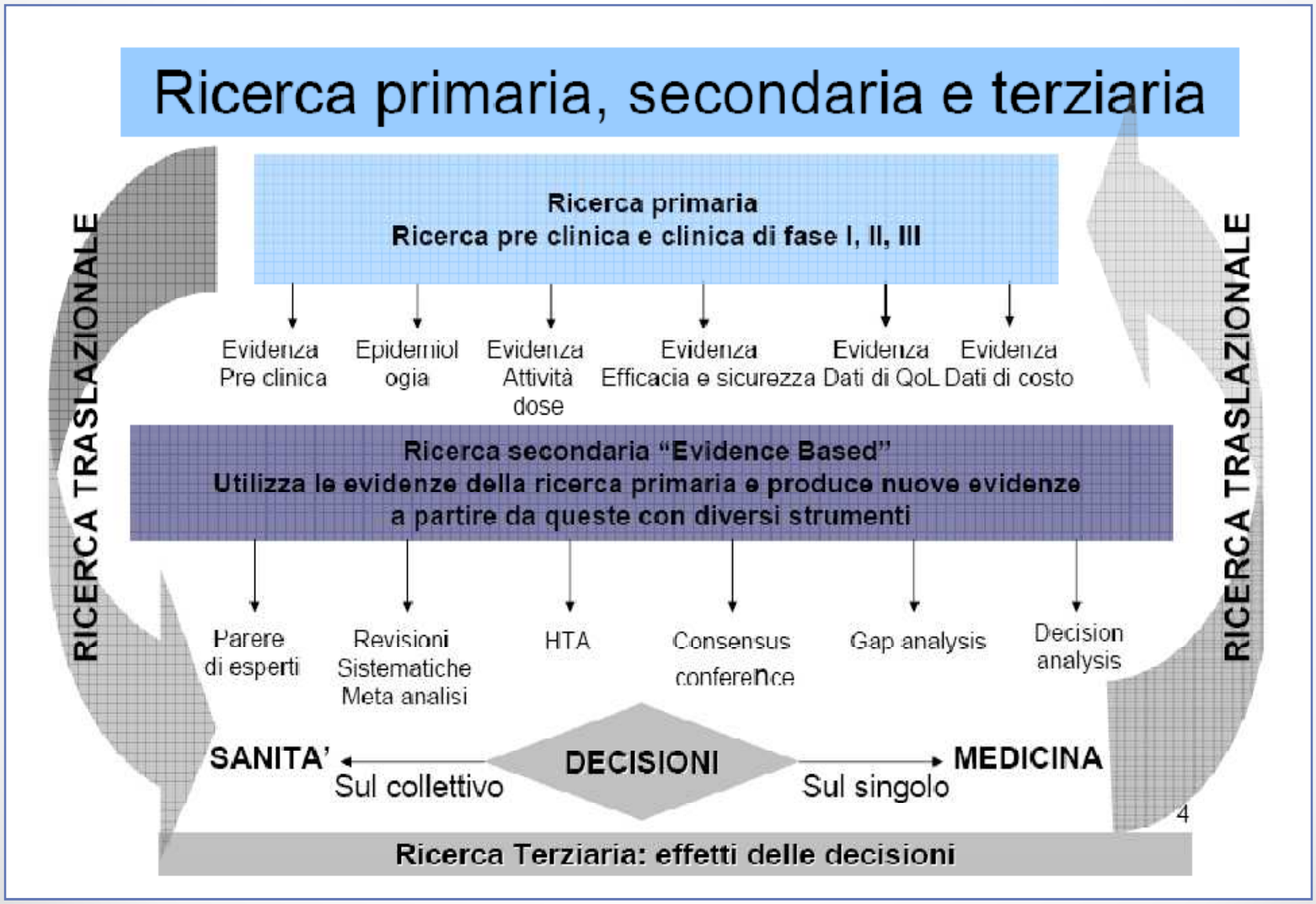
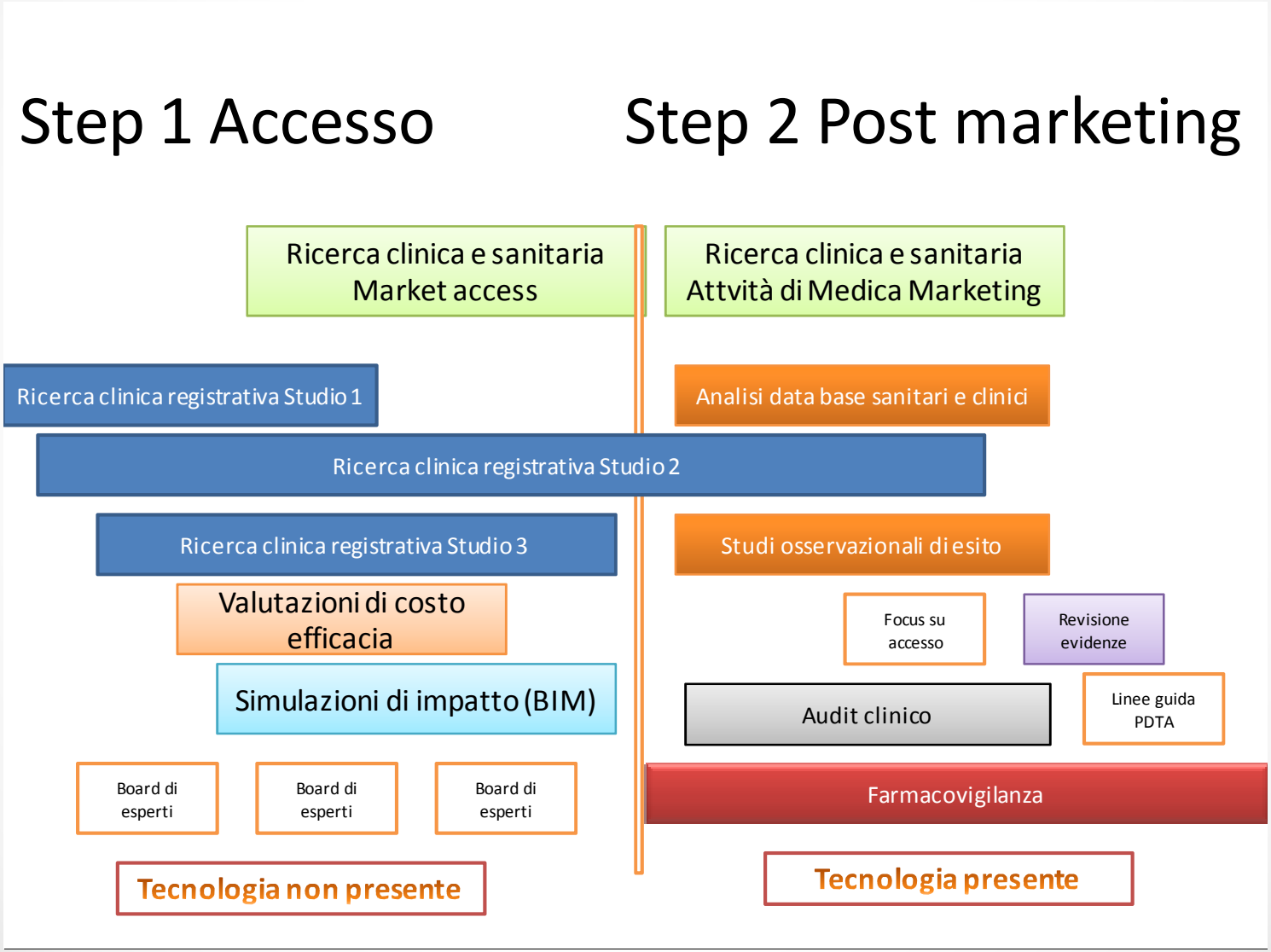
Ricerca clinica, evidenze, raccomandazioni e uso nella pratica clinica

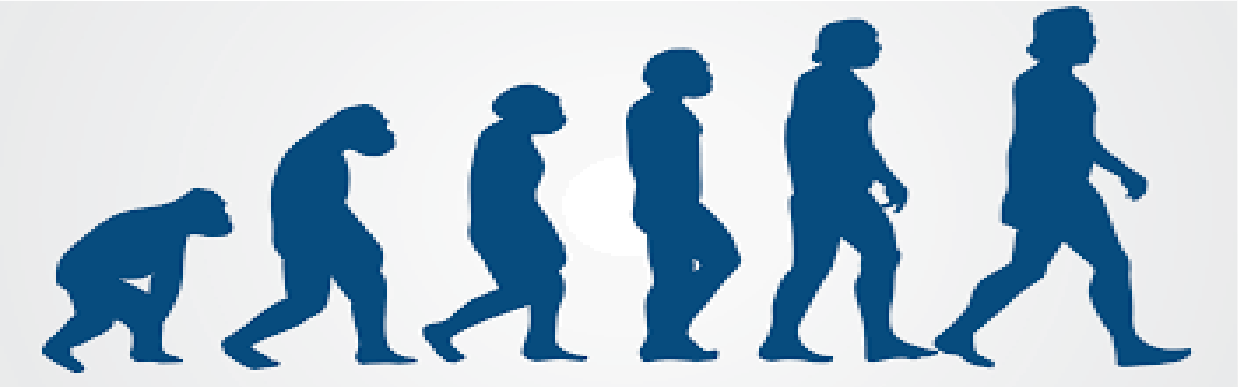


Approccio sequenziale



Approccio progressivo

- ✓ colmare gap alla registrazione e conferma quesiti (orfani)
- ✓ rispondere a nuovi quesiti (es. CER, esiti e/o costi)
- ✓ Sviluppo «uso» coerente con evidenze - adaptive licencing
- ✓ Rimuovere limitazioni e aggiustamento place in therapy e/o le condizioni di prescrivibilità (es. MMG / Specialista)
- ✓ monitoraggio (FV, Appropriatezza)



Evidenze e Decisioni

TAG ARCHIVES: EVIDENCE GENERATION (EVGEN)

What We Mean When We Talk About EvGen Part II: Building Out a National System for Evidence Generation

Posted on **May 3, 2016** by **FDA Voice**

By: Rachel E. Sherman, M.D., M.P.H., and Robert M. Califf,

In an earlier FDA Voice blog post, we discussed a pair of co
and connectivity – that are essential prerequisites for the cre
national system for evidence generation (or "EvGen"). In this
how we would apply these constructs as we go about buildir

http://blogs.fda.gov/fdavoice/index.tag/evidence-generation-evgen/

US: Interesse strategico del paese per definire in collaborazione con gli stakeholders le priorità strategiche per le nuove evidenze sui farmaci

Drug Design, Development and Therapy

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REVIEW

The role of health technology assessment bodies in shaping drug development

This article was published in the following Dove Press journal:
Drug Design, Development and Therapy
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Abstract: The use of health technology assessment (HTA) to inform policy-making is established in most developed countries. Compared to licensing agencies, HTA agencies have different interests and, therefore, different evidence requirements. Criteria for coverage or reimbursement decisions on pharmaceutical compounds vary; however, it is common to include, as part of the HTA, a comparative effectiveness evaluation. This type of clinical data might go beyond that required for market authorization, thus creating an additional evidence gap between the regulatory and the reimbursement submission. The relevance of submissions to HTA agencies is consistently increasing in a pharmaceutical company's perspective, as market prospects are strongly influenced by third-party payers' coverage. In this study, we aim

Italia : come usare in modo intelligente il patrimonio di strumenti e di cultura tra industria/università/regolatori/pazienti?

Il piano di sviluppo clinico del futuro

PASSATO	FUTURO
Sequenziale	**Progressivo**
Efficacy & Safety	**Esiti, costi**
Industria o accademia	**Industria & Accademia**
Prospettico	**Registri, Data base**