Statistics Jobs

La mia esperienza nell'industria farmaceutica

Silvia Barbi, Statistician at Novartis Vaccines

Bologna, 9 Maggio 2014

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Formazione ed esperienze accademiche

Laurea triennale in Statistica e Ricerca Sociale (luglio 2007)	• Tesi: *How the choice of different cut-offs influences the disagreement between quantiferon_TB gold and TSPOT.TB tests in the diagnosis of latent tubercolosis: A cross-sectional study* - in collaborazione con il Dipartimento di Oncologia, Ematologia e Patologie dell'Apparato Respiratorio, Università di Modena e Reggio Emilia
Assistente alla didattica (a.a. 2007/08)	• Lezioni in laboratorio del corso in Statistica e Calcolo delle probabilità
Scambio Overseas (a.a. 2008/09)	• Visiting Graduate Student alla University of Washington, Seattle WA, USA
Laurea specialistica in Scienze Statistiche (ottobre 2009)	• Tesi: *Cancer-associated genomic regions and microRNAs: a statistical investigation* - in collaborazione con il Department of Molecular Virology, Immunology and Medical Genetics, The Ohio State University, Columbus OH, USA
Licenza Collegio Superiore (ottobre 2009)	• Itinerari avanzati di carattere interdisciplinare
Docente a contratto (a.a. 2010/11)	• Breve modulo sulle fonti sanitarie all'interno del corso in Biostatistica

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Esperienze in azienda

CROS NT

(gennaio 2010 - gennaio 2013)

- Role: Statistician

NOVARTIS VACCINES

(febbraio 2013 – oggi)

- Role: Statistician

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Ricerca e Sviluppo (R&D) nel settore farmaceutico

Discovery: Identification of novel drug candidates

Pre-clinical: use of animals in drug development

Clinical development:
- Phase 1
- Phase 2
- Phase 3
- Registration
- Phase 4

Statistician

Statistician

Statistician

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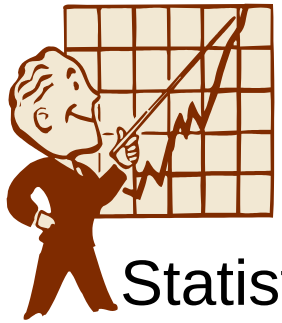
Come si colloca lo statistico nella ricerca clinica

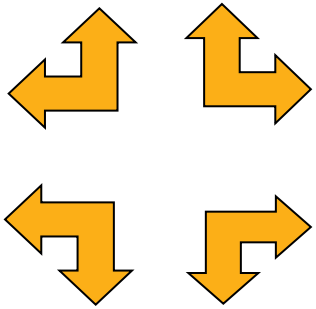
In una CRO

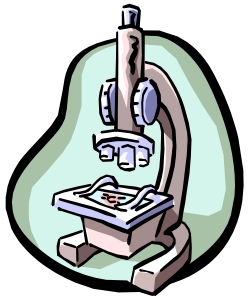
Investigator

Sponsor X



Statistician





Study Site

CRA

Data Manager

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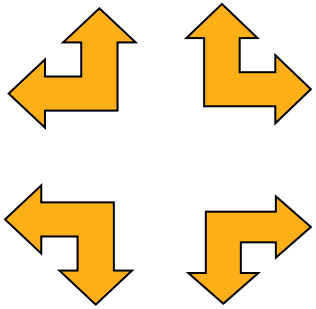
Come si colloca lo statistico nella ricerca clinica

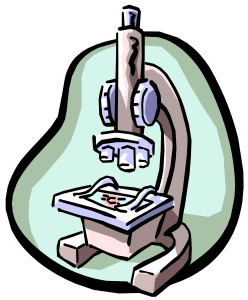
In un'azienda farmaceutica

Investigator

Pharma

Statistician





Study Site

CRA

Data Manager

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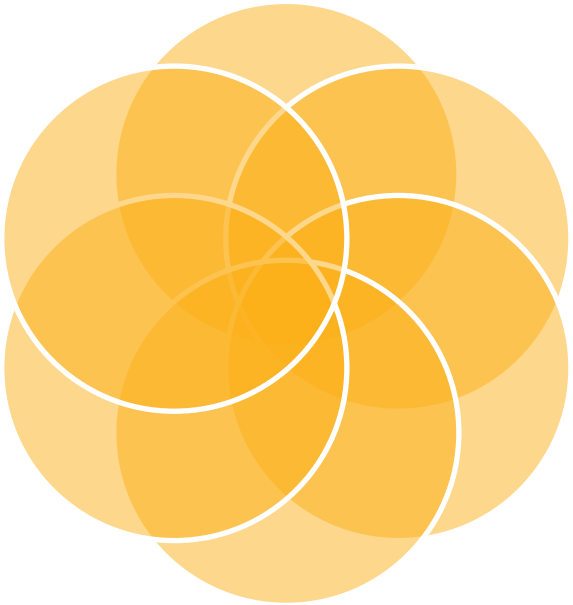
Il ruolo dello statistico nell'industria farmaceutica

Principali attività e responsabilità

Provides consultation and advice in quantitative/statistical, experimental design, and data management issues.

Interact with Health Authorities and external consultants as appropriate.



Works with the clinical team to develop clinical protocols, analysis plans and final study reports for clinical development projects.

Interact with Clinical Data Management as appropriate.

Plans, coordinates, and produces statistical analyses and summaries in support of product development.

Member of core clinical team, attend meetings and coordinates activities for assigned clinical trials with internal data management and programming staff, medical writing and regulatory affairs.

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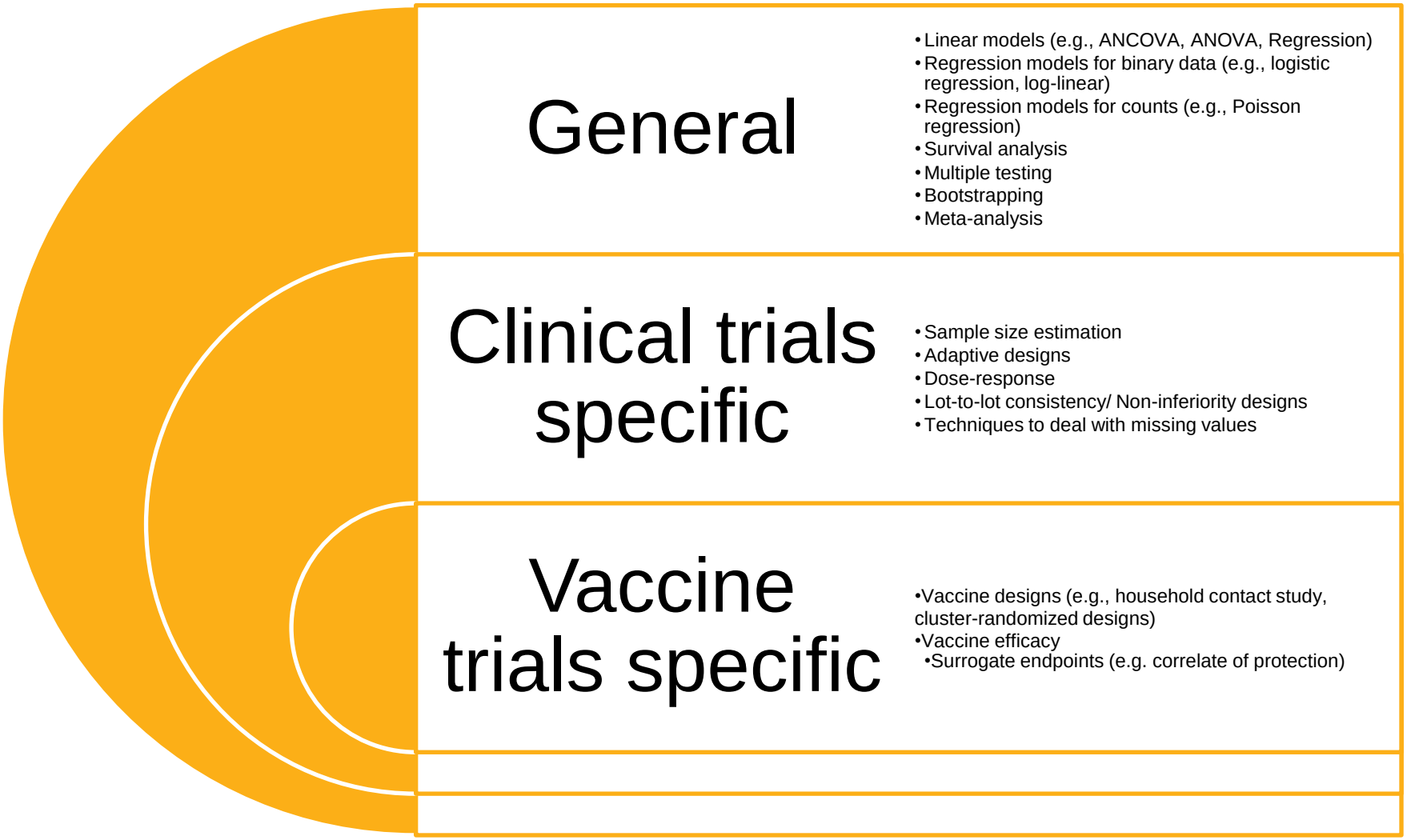
Metodologie statistiche utilizzate



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Background ideale

Education

- At least Master Degree in Statistics / Mathematics

Languages

- English, excellent spoken and written

Experience

- Demonstrated sound knowledge of statistical applications.
- Awareness of appropriate regulations and guidance documents.
- Preferably SAS programming knowledge.
- Some medical knowledge, especially in relation to specific vaccines area.
- Strong problem solving skills and sound statistical judgment. Technical capability to address common statistical problems arising in work.
- Attentiveness to detail.
- Strong interpersonal skills. Effective oral & written communication skills.
- Ability to effectively represent Biostatistics and Clinical Data Management in multidisciplinary meetings.
- Demonstrated ability to complete complex tasks on a timely basis with minimal supervision; well organized.
- Good project management skills.
- Good team player, good business ethics skills.

... Domande, dubbi, curiosità?

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