Ticino, a growing pharmaceutical area

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My job

- Local health authority for drugs, from development to detail market
- To guarantee high quality, efficacy and safety of drugs which are placed on the market and are available for patients
- Furthermore, to contribute to the provisioning of drugs to the country: namely to ensure that the legislative and economic framework is favorable to the development of pharmaceutical companies

- Fundamental research
- Toxicological studies
- Clinical studies Phase I
- Clinical studies Phase II-III
- R&D
- Regulatory affairs
- APIs Production
- Production of finished drugs
- Trading activities
- Post marketing surveillance

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Fundamental Research

- Institute for Research in Biomedicine (IRB)
- Laboratory of Experimental Oncology of IOSI (Oncology Institute of Southern Switzerland)

Institute for Research in Biomedicine (IRB)

Eight research groups

- Cellular immunology
- Chemokines: tissue expression, function and activity modulation
- Hematopoietic development
- Immune regulation
- Protein folding and quality control
- Signal transduction
- T cell development
- Viral replication, pathogenesis, and immunity
- FACS analysis

Laboratory of Experimental Oncology

Working areas

- Molecular pharmacology
- Drug development
- Cancer genetics
- Molecular biology

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Toxicological studies

- Inpharzam Ricerche (Zambon Group)
  - screening of NCE (antiinflammatory)
  - basic toxicology
- Other groups
- Actually 18 animal studies ongoing

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Clinical studies Phase I

- 3 CRO for study on healthy volunteers
  - ~ 30-50 studies / year
  - from first time in man to BE
  - register for healthy volunteers to encourage responsible participation, avoiding potential negative consequences for the subject's health and ensuring high-quality research
- Phase I in Oncology (first time, dose finding)

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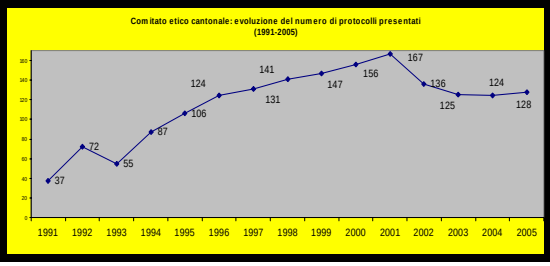
Clinical studies Phase II-III

- 80 – 100 clinical studies / year
- Oncology, cardiovascular diseases, HIV
- Local ethic committee



Response time of the Ethic Committee

- Mean response time: 14.3 days
- 10 days or less in 57% of cases
- Shortest time: 5 days
- Longest time: 42 days

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R&D

- ± all manufacturers (except pure contractors)

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Regulatory affairs

- Several CROs and consultants

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APIs Production

- 5 licensed companies
  - chemical synthesis
  - fermentation
  - botanical extracts
- Most of them: contractors
- 2 FDA approved

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Production of finished drugs

- 25 licensed companies
  - solid dosage forms
  - liquids (sterile, non sterile)
  - aseptic processing
  - micronization technology
  - medical - external labs
- Contractors and marketing gases authorization holders
  6 FDA approved

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Trading activities

- 100 licensed companies
  - marketing authorization holders for Swiss market
  - drug products distributors for Swiss market
  - APIs traders
  - drug products traders

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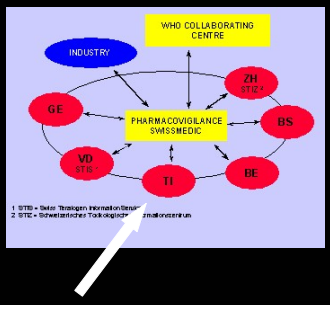
Post marketing surveillance

- Regional Centre for Pharmacovigilance



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International acknowledgment

- EU MRA for GMP, MOI for GCP
- US MOI for GMP
- CAN MRA for GMP finished products
- PIC Membership

The pharmaceutical world of Cantone Ticino

- Almost complete spectrum of activities
- Small and Medium Enterprises
- ~ 350 licensed companies
- ~ 3000 employees
- ~ 1-1.5 Billion SFr