Collecting Safety Data

Anders Svensson MD,PhD
Head of Global Cinical Development – CV/Metabolism
F. Hoffmann-LaRoche, Basel, Switzerland

Randomized prospective trials – the gold standard

- Defined population with known baseline characteristics
- Duration of exposure is known
- Events are collected prospectively, and adjudicated for consistency
- Concommitant treatments are captured
- All patients/treated individuals should be captured in ITT
- Expensive!
- Still limited number of patients to capture weak signals

Can the prospective randomized trial be improved?

- Not the principle – but the way we do these trials

  - Costs must come down
  - Complexity must be reduced
  - Real life should be reflected
  - Speed vs. Long-term data must be optimized
  - Benefit-Risk evaluation must be reliable, and reasonable

How can we improve/adapt the RCT?

- Globalization? Will this drive costs and complexity? Not necessarily.
- Focus on patients – not investigators/sites
- Optimize data collection – an area that can be improved
  - What we collect (far too much in many cases)
  - How we collect data (electronic, remote capture on line, directly from patients, labs and investigators)
  - How we handle data – every conceivable analysis is performed, just in case

Other Approaches

- Cohorts that are prospectively followed in Health Care Systems
  - Non-randomized, brings bias
  - Not well defined
  - Events not systematically captured
  - Reflects real life
  - Large numbers will increase the ability to detect signals
- Data mining of large databases
  - Ideally when/if there are national health care databases, electronic records of millions of people (NHS has been aiming for 10 years to get this going). Ideally no drop-outs when people move, change doctor or hospital.
  - Strength in numbers, ability to rapidly detect signals.

We Innovate Healthcare