Top 3 Considerations – Legal & Policy

- Put every project in the broader context
  - Reimbursement
  - Commercial positioning
  - Regulatory and life cycle management plans
- Ensure compliance as much as possible to allow further use of data
- Seek overall robustness and reliability of the data -- and realise you will not fully control use

Peter Bogaert (pbogaert@cov.com)

Top 3 Considerations – Compliance Implementation

- Place patient benefit first (Ethical goal):
  - Maximizing value for patients: that is, achieving the best outcomes at the lowest cost. **Requires a fundamental departure from the past.**
  - Treat not only a disease but also the related conditions
  - Include RWE in clinical trial development and collaborative approach with payers to assure best common results

- Strategic approaches
  - Need to balance risk/benefits of conducting own studies versus external studies conducted either by Payers or Centers
  - Legitimacy of results needs to be assured
  - Market Access assumptions to be developed earlier than before in clinical studies development cycles (Phase II, versus phase III only)

- Tactical approaches
  - Studies should be conducted under M&D or HEOR
  - Oversight/governance, validation, data privacy, use of data to justify pricing model, competitors' data
  - Involvement of Healthcare Technologies agencies: ensure level of maturity in terms of data privacy knowledge and resources
  - Post Launch: Data collection Platforms need to be non-promotional and respectful of data privacy

Top 3 Considerations: Market Access

- Know the evidence needs of your payer stakeholders
  - Significant penalty for non-comparative studies
  - Be prepared to provide discounts to facilitate access timing
  - National payers will look to capitate your label if you get it wrong
- Conduct Real world studies to address payer uncertainties:
  - Comparator drug used in registration trial is often not used in several markets
  - Evaluating the long term benefits of a drug – safety and efficacy
  - Be very careful how you design and implement studies
- Real world data is unlikely to have a major impact on pricing of a new drug but may open up reimbursement
  - Can be linked to managed entry agreements although outcomes deals are rare due to complex implementation challenges
  - Particularly relevant for conditionally approved drugs in oncology where survival data is immature