Alternative views on data transparency

Uli Burger
Current situation

- EMA attempts to publish in future CSRs and raw data in an uncontrolled manner for all studies included in submissions from 2014 onwards

- Various companies attempt to release CSR and raw data in a much more controlled fashion to the public starting 2013 (GSK, Roche,...)
  - Attempt to protect patient confidentiality and commercially confidential information
  - Attempt to maintain scientific rigor
  - Decision to get access to data made by independent group
  - Access limited to SAS based system to limit capabilities of downloading datasets

- Various journals get more strict on releasing underlying data and have independent re-analysis done
Current situation

• Ethical demand
  – Patient data not property of individual companies. Value of data should be maximized as much as possible by making available to 3rd parties
  – Patient confidentiality has to be strictly maintained

• We need to support both aspects, but how?
  – How open should we be upfront?
  – How many rules should we put in place?

• It will have an impact on how Pharma is operating and how biostatistics within Pharma is operating. Can we influence this?
EFSPi versus EFPIA positions

• We see a lot of discussions at various parties. Do we in EFSPi need always to be aligned?
  – Example: Commercially confidential information

• Restricted position:
  We should be always aligned with EFPIA/PhARMA view

• More flexible position:
  Although we need to be aligned within each company but as a function we should be independent and have more of a statistics view
For each group:

• Next four topics deal with transparency and directly beyond:
  – What will it mean to us?
  – What will it do to us?
  – Where to align, and with whom?
  – Where to stand “on our own”?

• What is our position?
  • As a statistician and member of EFSPi
  • As a statistician and employee of a pharmaceutical company
Some controversial position I

Access to data?

• Trust position: Access should be unlimited
  – Medical and biostatistical community will go through some tough years but then will learn best how to deal with this situation
    • No limitation for access
    • No limitation that only statistical trained personal should get data
    • Journals will learn to separate good and bad research

• Restricted position: Access only very limited and controlled by companies
  – Companies could basically perform additional analyses for third parties
  – Access for meta analyses limited and restricted to minimum of data
  – Strict rules in place when access will be given and only for projects with undoubted high scientific value
Some controversial positions II

Publication remit

• Independent reanalysis of data not necessary as there was never a problem for pharmaceutical industry there (modulo normal mistakes).

• Quality of academic publications with regard to statistics usually lower

• Restricted view
  – We try not to publish in journals which require publication of datasets and/or re-analysis of paper results by independent academic institutions

• Offensive view
  – We actively support this but would like to request published review of results of this request to see if it was justified
    • How many times differences were found, and if
    • how many time academic analysis was right (after reconciliation)
Some controversial positions III

Who is doing phase III?

• When academic world needs to do analysis may be they can do first analysis as well?
  ⇒ Phase III will in future be performed by academia and only sponsored by industry by providing drug
  – Industry will get used to lack of control
  – This will cover all registration studies in future

• Academia will need to change structures for this and may be experienced statisticians from industry need to return to academia. May be cost effective for industry

• Will effect not only biometrics but all development in pharma as development as a whole may be moved to academia

• Alternative: Continue in current format
Some controversial positions IV

One industry solution?

• We have one industry solution for every company on data transparency (for those who would like to do it...)
  – Needs discussions...
  – Needs time...
  – How far should we harmonize?

• Every company has its own solution
  – The company with the most liberal solution will “win”, all others will be critized.
  – How can we avoid that?

• Companies may get set up against each other in case of re-analyses
  – How can we avoid that controversies will back fire on Statisticians?
  – Do we need a trusted third party in such cases?