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 ?

    $\Rightarrow$ 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?