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

Access to Data ?

- Take home messages:
  - Statisticians should focus more at quality than trying to increase trust
  - No matter which solution the workload will increase:
    - Reactively (in case of unlimited access)
    - Pro-actively (restricted access by companies)
  - If any, statistician might be favoring an in-between position:
    - restricted access through independent party

	Unlimited Access	Restricted access company controlled
what will it mean to us	not very different	not very different
what will it do	increase workload but in reactive mode	increase workload but in pro-active mode
where to align	journals	reputations

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)

Publication remit ?

- Take home messages:
  - Statisticians should take independent, balanced view on publication/re-analysis remit:
    - focus should be on statistics
    - share view with EFPIA and others
    - be open to collaboration
  - EFSPI should revisit JAMA policy of demanding independent re-analysis
    - EMA transparency initiative provides opportunity:
      - “would JAMA still request it when the one company would analyse another company’s data already through EMA?”

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

Who is doing Phase 3 ?

- Take home messages:
  - Statisticians in general would not feel the need for having only academia perform clinical trials
  - But if, Then:
    - Perception of public to clinical trial results would increase
      - Publication remit and unbiasedness solved
      - Yet, Is academia independent? And what if contracted to (commercial) CROs?
    - Statistician in Industry would get on different, higher level:
      - more seniority; more visible, more important, needs to

academia will perform clinical studies, pharma will deliver drugs only	Pros	Cons
	better perception	are academia independent ?
	publication easier	are academia able?
	sensitivity analyses	academic means CRO
	unbiased SAP	limited in 1st analysis and subgroup
	win some support on some discussion points with the company	not covering enough safety

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	If only academia would perform trials
what will it mean to us	higher seniority in Industry, other in Academia; negotiation
what will it do	increase visibility/importance statistician within the company; no continuity plan within company; less general drug development knowledge
where to align	alignment between statisticians company and academia will be challenged by company

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?

One Industry Solution ?

- Take home messages:
  - One industry solution is best for Industry and EFSPI
    - To implement retrospectively is difficult
    - Same set of principles for everyone; details may vary
    - Same set of anonymisation rules
    - Same process for Industry and Academia
    - Will better enable consistency in secondary, (re-)analyses
  - Still guidance needed on best practices on re-analysis
    - Good scientific purposes, but stress exploratory nature
    - Differentiate between analysis and interpretation
    - Yet, new area for pharma statistician
    - Acknowledgement of competitive environment