

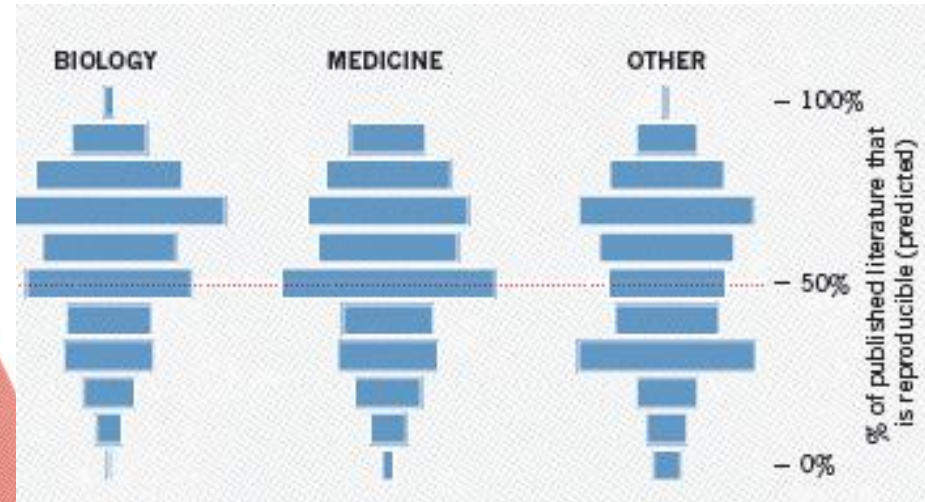
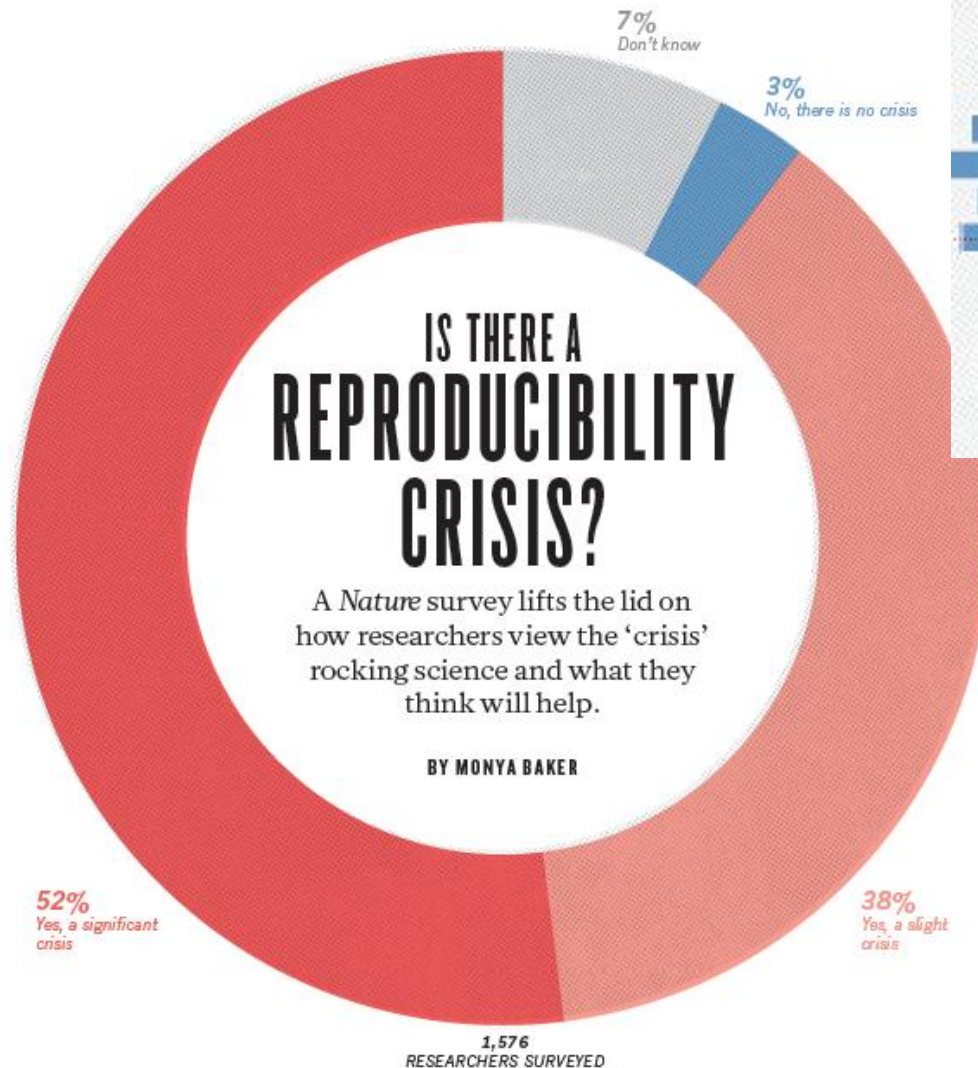
# Publication of research

## Rules, requirements and raw data

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# Why do we need to rethink the way we communicate science ?



# What are the essentials of science ?

- Plan your experiments well
- Reproducibility
- Dose-response (most relevant in toxicology) !
- Do not speculate beyond what your data tell you
- Always question your results
- Use appropriate and well evaluated methodology fit for purpose

- Scientific publishing is big business and the new journals need to be filled
- Pressure to publish for promotion, funding
- Less rigor in the editorial processes and peer review
- Press releases, publication bias
- General issues with reproducibility, plausibility
- Funding instruments often require to address specific problems, away from hypothesis-driven research

# Questions to be asked when evaluating a manuscript (eg ARRIVE guidance)

- Hypothesis clearly outlined, plausible and based on valid science ?
- Adequate methodology that is clearly described ?
- Logical experimental approach and detailed description of results ?
- Adequate interpretation, do all conclusions have data support ?

# Raw data are essential for following conclusions

- At present, raw data are not available for most publications except for studies required for regulatory purposes (toxicology)
- Availability of raw data requires reorganization in many labs and often a change of mind sets of researchers
- Storage space is not an issue; therefore, raw data can be made available in electronic form and a standard format (for example see reports on guideline toxicity studies) as annexes to any publication

# Study protocols

- Availability of study protocols before starting actual experiments are as important as are raw data
- Study protocols define the approach to tackle scientific problem by outlining experiments (no. of repeats, statistics, methodology, evaluation)
- Protocols should also be available to the scientific public on specific media before starting experiments
- Modifications to published study protocols can be justified when required

# Publication of negative results

- Scientific journals are not interested due to “low impact”
- However, a well conducted experiment with negative results may provide much relevant information
- Again, web-based platform can be developed to give opportunity of access to such results
- Scientific publishers seem to slowly become interested in such “data repositories”



# **Weight of evidence (WOE) approach in toxicology**

- The weight of evidence evaluation is a determination of what is a reasonable conclusion in view of all available information.... while exercising one's best judgement.
- Requires detailed justification of conclusions based on the available science

# WoE quality scoring approaches (Range 0 – 4)

- General experimental design e.g. number of animals per dose group and use of negative/positive controls
- Mode of application (stability, dose, medium, route of administration, duration, timing)
- Suitability of sampling methods, sampling times and procedures
- Suitability of assessment methodology
- Suitability of biochemical and functional measurements
- Accessibility of raw data
- Appropriate statistics

- Needs to include
  - ◆ Dose-response
  - ◆ Magnitude of changes
  - ◆ Persistence of changes
  - ◆ Consistency of changes when several endpoints measured
  - ◆ Relevance of endpoint to disease development
  
- Separate scoring and weighting for:
  - ◆ Biochemical changes clearly associated with adverse effects
  - ◆ Organ weight changes
  - ◆ Gross changes
  - ◆ Pathology

# Symptoms of „Pathological Science“

- The maximum effect that is observed is produced by a causative agent of barely detectable intensity, and the magnitude of the effect is substantially independent of the intensity of the cause.
- The effect is of a magnitude that remains close to the limit of detectability, or many measurements are necessary because of the very low statistical significance of the results.
- There are claims of great accuracy.
- Fantastic theories contrary to experience are suggested.
- Criticisms are met by ad hoc excuses thought up on the spur of the moment
- The ratio of supporters to critics rises up to somewhere near to 50% and then falls gradually to oblivion.

**Irving Langmuir, 1930**