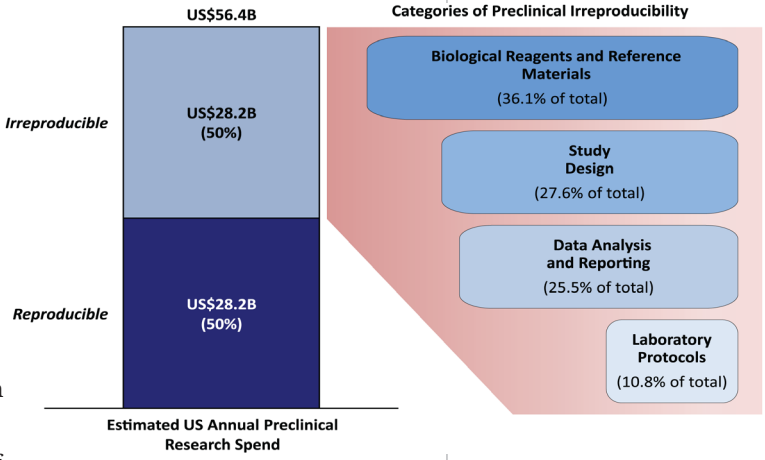
What We Are Reading

„The Economics of Reproducibility in Preclinical Research“

Freedman LP, Cockburn IM, Simcoe TS (2015) , The Economics of Reproducibility in Preclinical Research. PLoS Biol 13(6): e1002165. doi:10.1371/journal.pbio.1002165
http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002165

Publication Abstract

Low reproducibility rates within life science research undermine cumulative knowledge production and contribute to both delays and costs of therapeutic drug development. An analysis of past studies indicates that the cumulative (total) prevalence of irreproducible preclinical research exceeds 50%, resulting in approximately US$28,000,000,000 (US$28B)/year spent on preclinical research that is not reproducible—in the United States alone. We outline a framework for solutions and a plan for long-term improvements in reproducibility rates that will help to accelerate the discovery of life-saving therapies and cures.



Our Take Home Message

The sheer amount of irreproducible data, 50% mentioned in this publication, up to 80% according to other sources, seems to be extremely high. My immediate gut feeling, based on 20 years in Life Science R&D, would be “way to high” and certainly not representative for the average of Life Science R&D.

So, everything is fine and well, just some outliers? Not quite, for two reasons.

First, having a closer look at the study details (see graphic below) really gets you thinking again. Let’s take the reference materials as an example, accountable obvious-

Irreproducible Preclinical Research exceeds 50%

ly for quite a lot of irreproducibility. Getting better marks in this area would require better procedures. However, clear cut rules how to handle reference materials during purchase, storage or lab operations are by no means a standard in the discovery units we visit. And the next level of quality, some investigational data as a rational basis why reference materials are handled exactly in this way, is practically of rarity value. The same is true for the other sources of irreproducibility. The positive gut feeling might be just the result of never having looked close enough.

Basic Quality Procedures would make a Difference

Second, even significantly reduced irreproducibility, say down to 20%, would still be a problem. The industry considers their R&D processes to be “data driven”. Extremely costly decisions are taken on the basis of presumably solid data and results. What is the impact of 20% irreproducible data on those decisions? How many of those decisions are shaky or just plain wrong due to quality issues with the underlying data set? And how about error propagation of cumulating irreproducibility? Is there some point of no return, a point on the R&D value chain when “data driven” mutates to “throwing dice”?

Shaky Results driving Shaky Decisions?

We do believe that the quality aspect of drug discovery is key to project success and to improved R&D productivity. And exactly in this field, quality in drug discovery, is significant room for improvement throughout the industry.