

# TRIAL

## TRIVIA

We all know there is nothing trivial about clinical trials.  
This issue of *Medical Writing* says it all.  
But let's have some light fun and try answering the short quiz below.

- 1 What is the earliest documentation of a trial?
- 2 What is the largest pre-approval trial in terms of number of participants? The smallest?
- 3 What is the longest running trial?
- 4 What is the most expensive trial?

Answers  
on  
page 65

I hope you enjoyed this quiz and this MEW issue. Thank you to all our contributors and the editorial team – Editor

## Trial Trivia Answers *from page 53*

### 1. What is the earliest documentation of a trial?

No, it wasn't James Lind. Allegedly, the Bible documented the first human experimentation in the Book of Daniel 1:12-15. "Test your servants for ten days; let us be given vegetables to eat and water to drink. Then let our appearance and the appearance of the youths who eat the king's food (meat and wine) be observed by you, and deal with your servants according to what you see."

It was an interventional, open-label, active-controlled, parallel-group comparative study. The outcome is summarised by Arun Bhatt in his paper entitled Evolution of Clinical Research: A History Before and Beyond James Lind. The paper also describes the origins of the use of placebo and the double-blind study design.<sup>1</sup> Definitely a delight for history buffs!

But what about my hero James Lind? He was the Scottish doctor who researched the treatment of scurvy among British sailors. The documentation in his book *A Treatise of the Scurvy* earned him the title of "Father of Clinical Trials".<sup>1-2</sup> Because of his research, vitamin C became part of our daily diet and the British got nicknamed "limey" as limes and other types of citrus fruits became staple on British naval ships.

### 2. What is the largest pre-approval trial in terms of the number of participants to date? The smallest?

The largest trial is supposedly the **Rotavirus**

**Efficacy and Safety Trial (REST)** registered under NCT00090233.<sup>3</sup> It enrolled a whopping 69,274 infants aged 6 to 12 weeks. The COVID-19 trials also ranked among the top ten, with at least 30,000 participants.<sup>4</sup>

Generally, vaccine trials require a large number of participants. At the other end of the spectrum, trials in orphan drugs understandably have low numbers of participants, sometimes fewer than 15.<sup>5</sup> Having worked in both Vaccinology and Rare Disease areas, I am privileged to have been involved in projects at these two extremes. Most trials fall somewhere in between.

### 3. What is the most expensive trial?

I can't find a straight answer. A survey of 138 pivotal trials used as basis for approval of 59 new therapeutic agents by the FDA from 2015 to 2016 showed median estimated cost of \$19.0 million (range < \$5 million to \$346.8 million).<sup>5</sup> However, more recent reports actually place the median cost at \$648 million for new cancer drugs.<sup>6</sup>

### 4. What is the longest-running clinical trial?

This website<sup>7</sup> lists the 10 longest-running clinical trials, with the study on **Botulinum Toxin for Involuntary Movement Disorders** as the record holder. Clinicaltrials.gov records show that this trial (NCT00001208) supposedly started in 1989 and is still recruiting to date.<sup>8</sup> This means this trial even predates EMWA.

## References

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