



Time well spent? A comparison of the work associated with collecting primary and secondary outcomes

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Lots of trials, they all need data

- **There are around 25,000 trial results published every year¹**
- **The number of things we measure is increasing²**
- **Data management accounts for a lot of work; one estimate is that over a 3rd of hours spent on trial is spent by data managers³**

1. Bastian et al PLoS Med. 2010; 7: e1000326.

2. Getz et al Am J Ther. 2008; 15: 450–7.

3. O'Leary et al Clinical Trials. 2013; 10: 624–32.

But are these data informing decisions?

**CLINICAL
TRIALS**

DATA MANAGEMENT AND TRIAL CONDUCT

Clinical Trials 2013; 10: 624–632

Data collection in cancer clinical trials: Too much of a good thing?

Erin O'Leary^a, Hsien Seow^{a,b}, Jim Julian^{a,b,c}, Mark Levine^{a,b,c} and Gregory R Pond^{a,b,c}

Background Substantial staff time and costs are incurred in the collection of data for cancer clinical trials. Anecdotal experience suggests that much of these data are never used in the analysis or reporting of a trial.

Purpose To quantify data items collected in cancer clinical trials and calculate what percentage is used in subsequent published manuscripts.

Methods Cancer clinical trials completed by the Ontario Clinical Oncology Group (OCOG) between 2003 and 2012 and the corresponding primary outcome publication were identified. The number of data items collected on each trial's case report form (CRF) was counted and sorted into 18 categories including eligibility, baseline characteristics, medical history, toxicity, and recurrence. The data items were then counted within the corresponding published manuscripts to determine percent of data used overall and within each section.

Results In all, 8 trials, with 9 corresponding publications, were evaluated. The CRF analysis revealed that the total collected items per subject ranged from 186 to 1035

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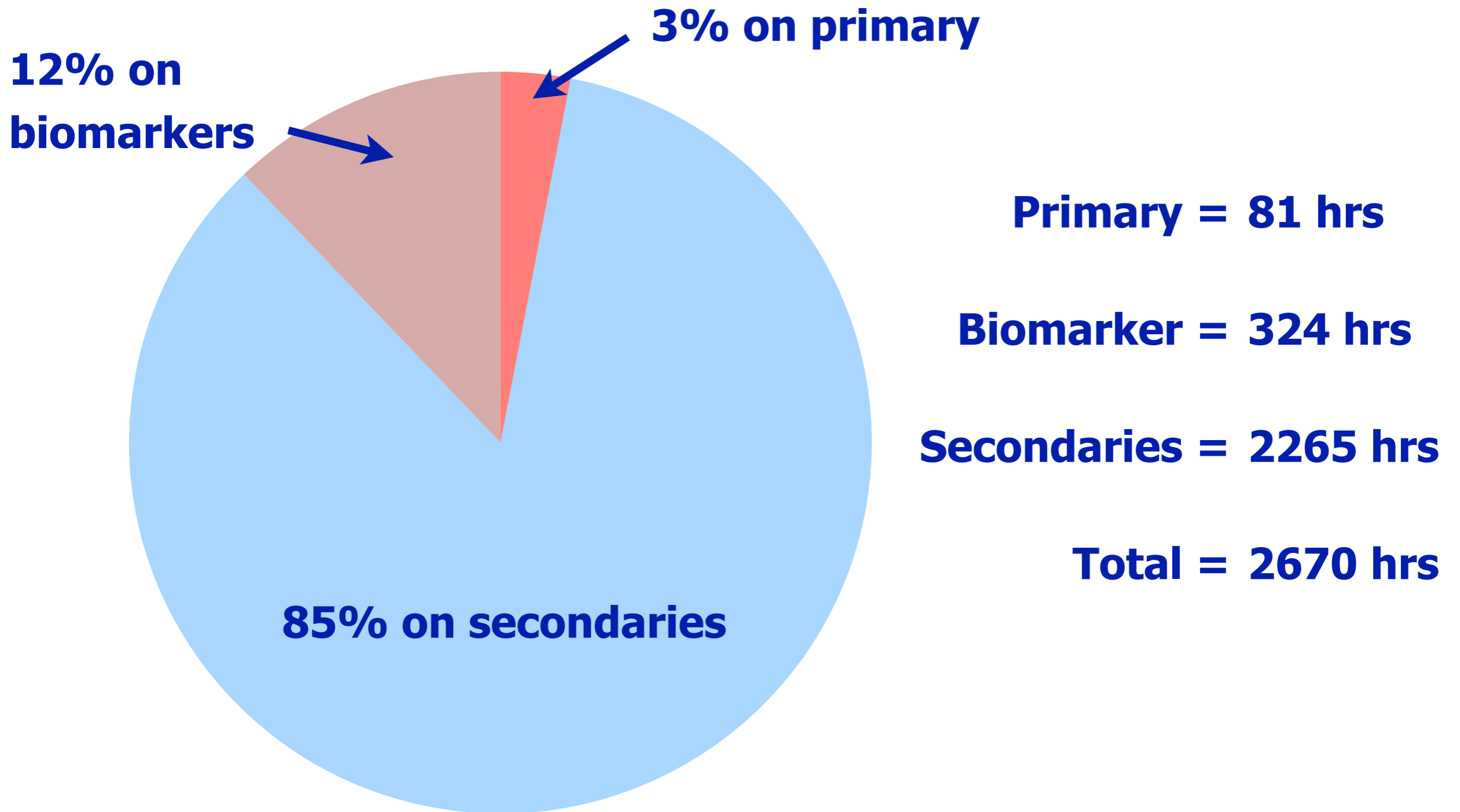
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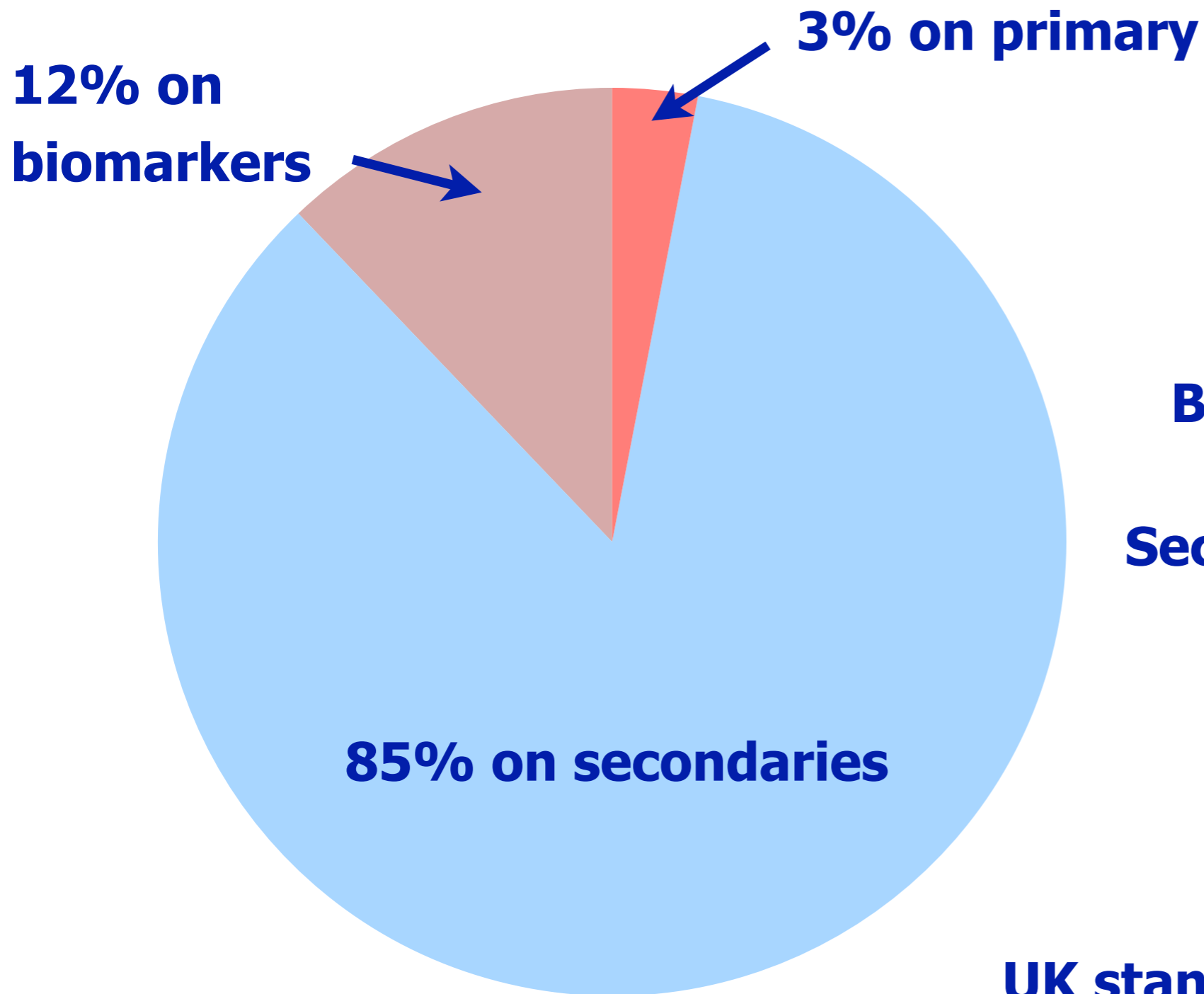
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Ongoing international trial: data collection



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Primary = USD 5,103

Biomarker = USD 20,412

Secondaries = USD 142,695

Total = USD 168,210

UK standard cost for a research nurse is around USD 63 per hour

So, let's look at a bigger sample

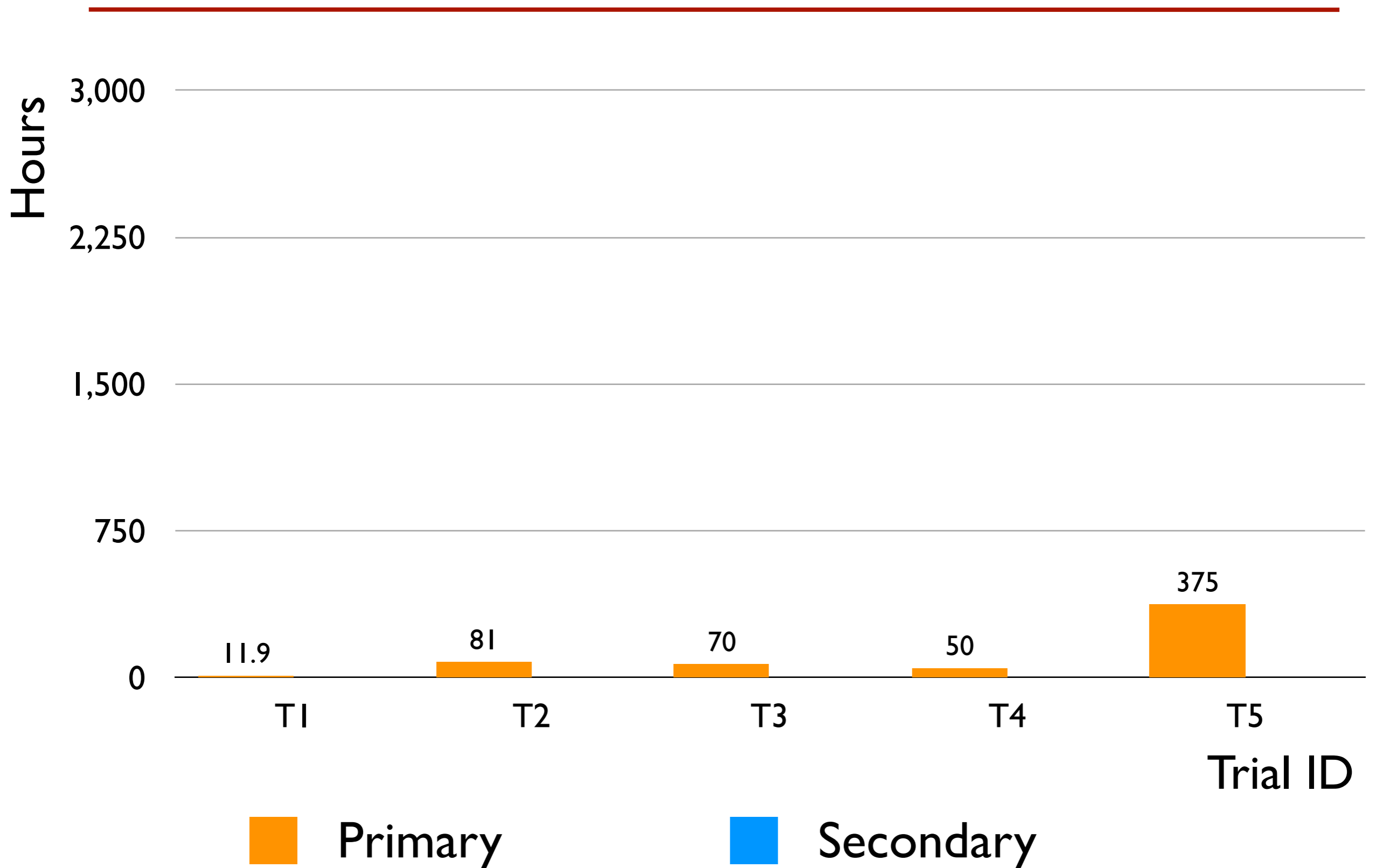
- **Random selection of 115 protocols for publicly funded, randomised trials published 2010-2014 (~24 per year).**
- **Primary and secondary outcomes extracted from protocols.**
- **Data on time to complete each outcome were sought from protocols, the corresponding author, or from trial managers familiar with the outcome.**

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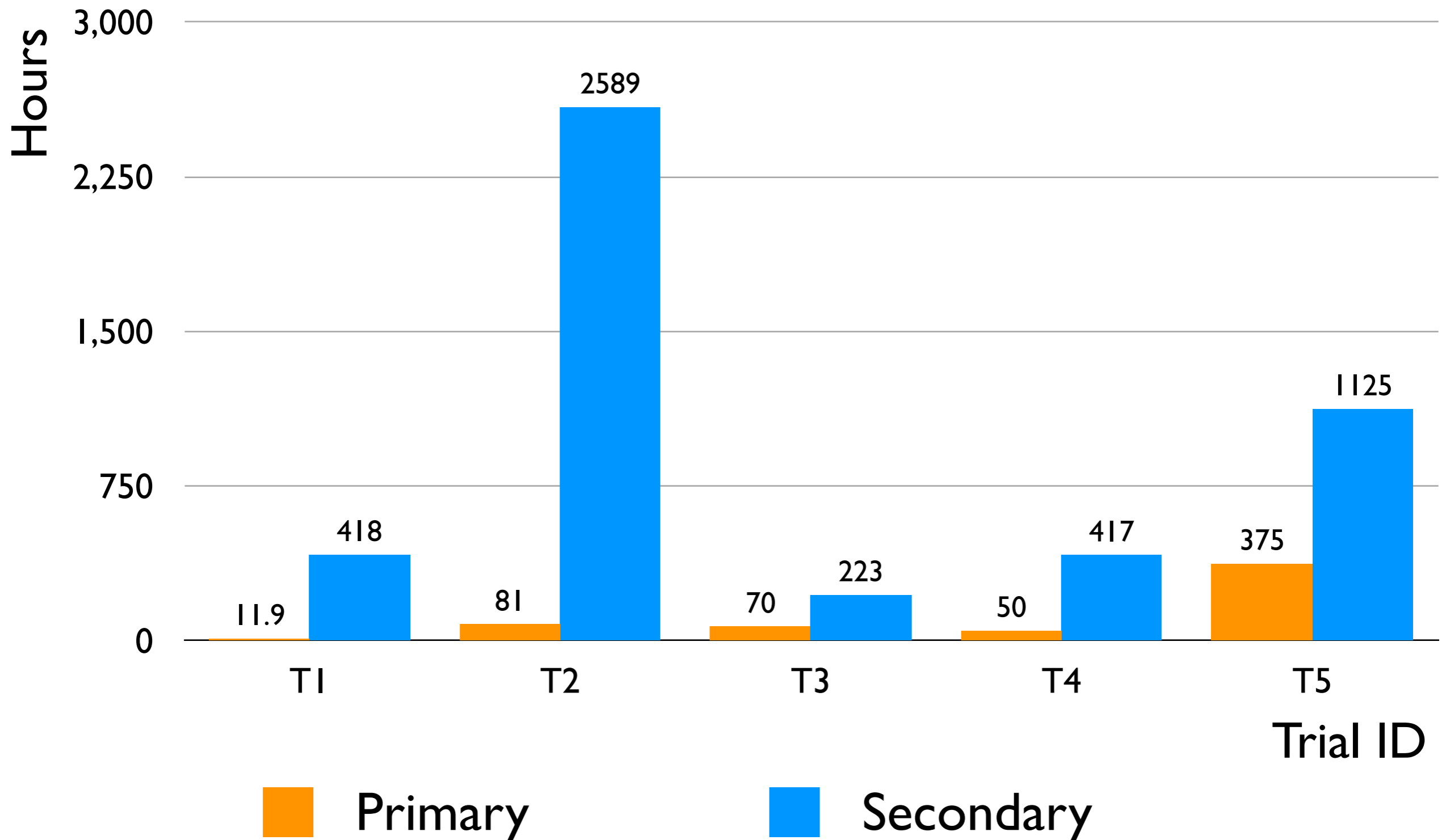
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We've looked at 20 trials so far
(sample size: 75 - 4000)

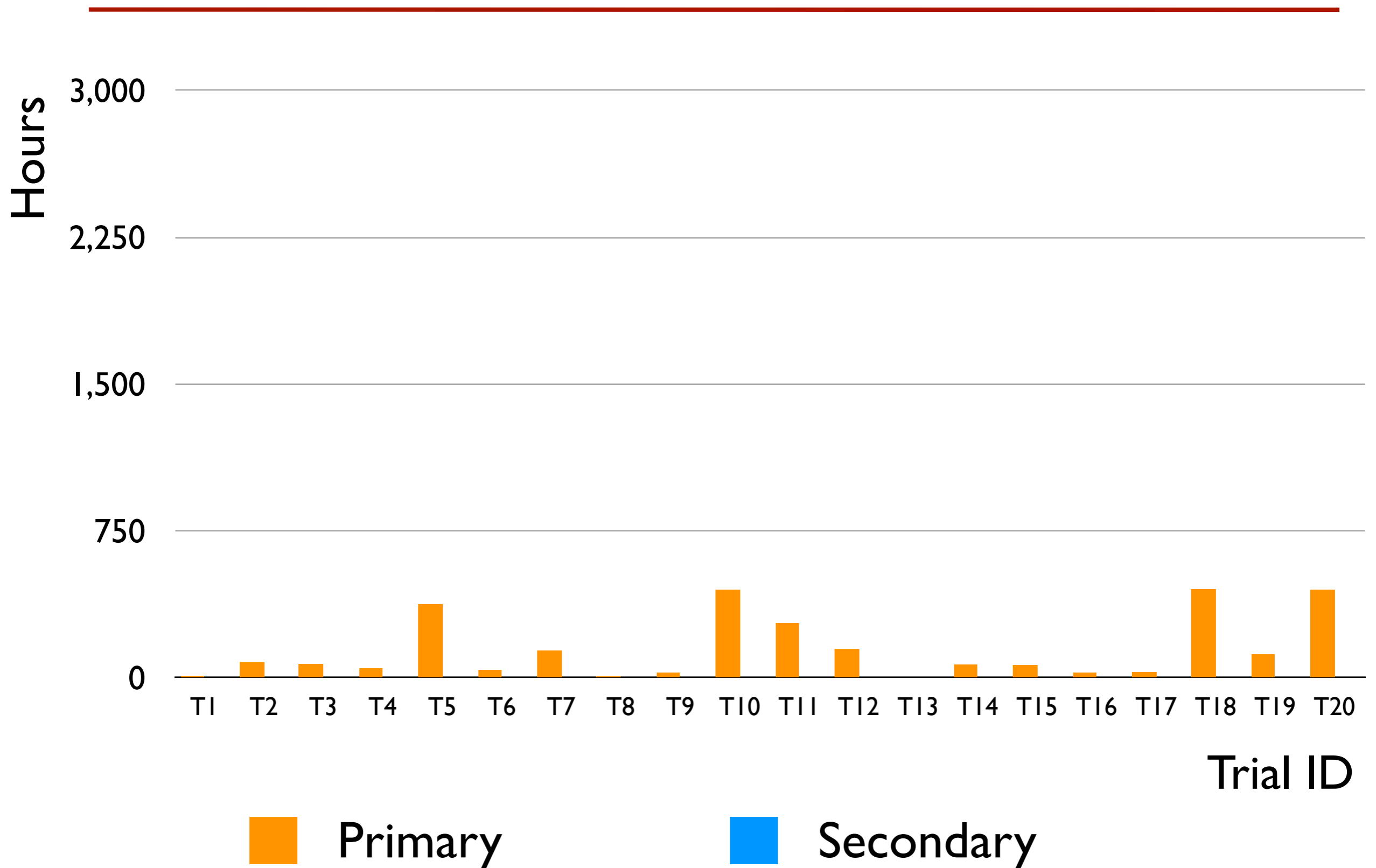
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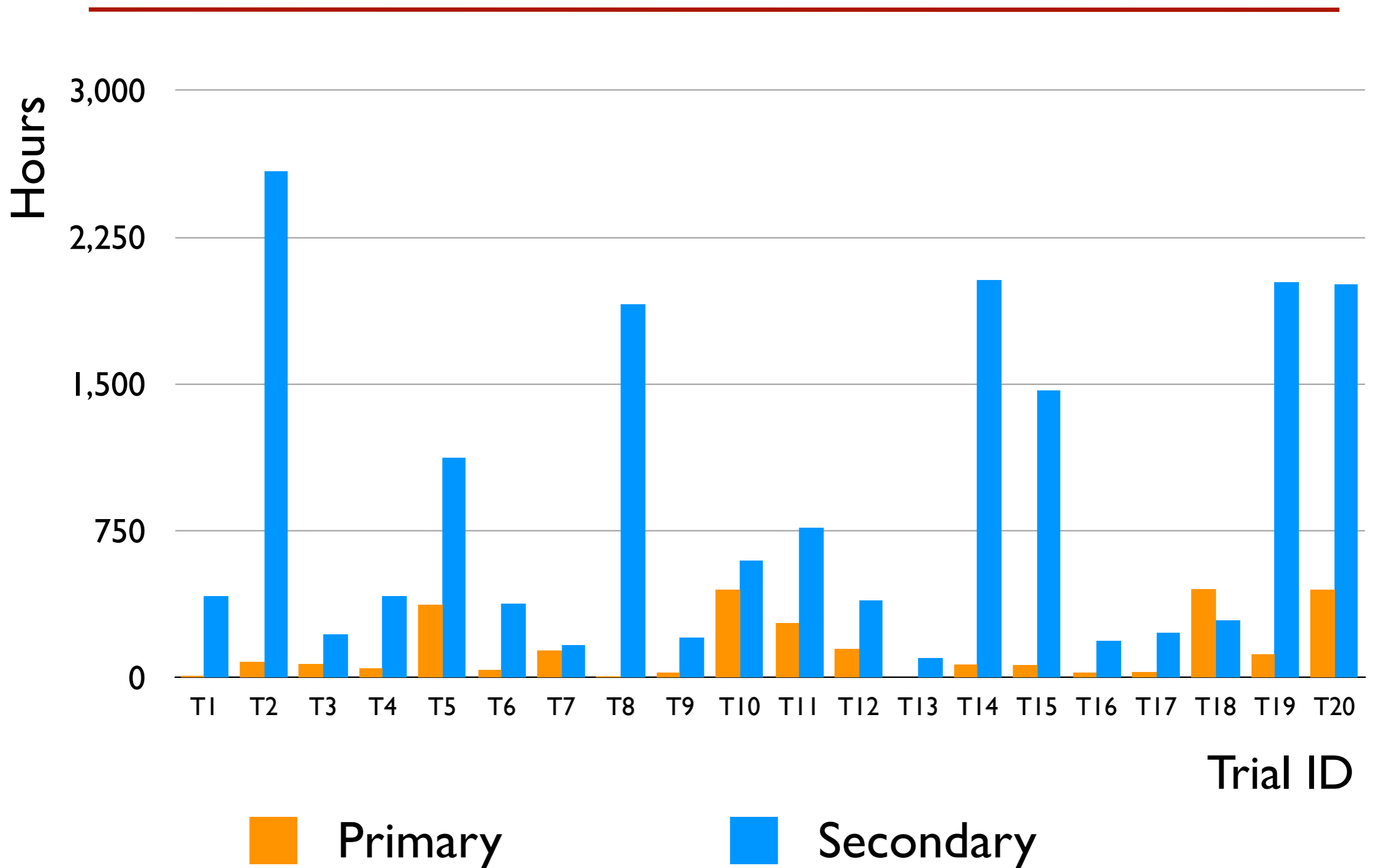
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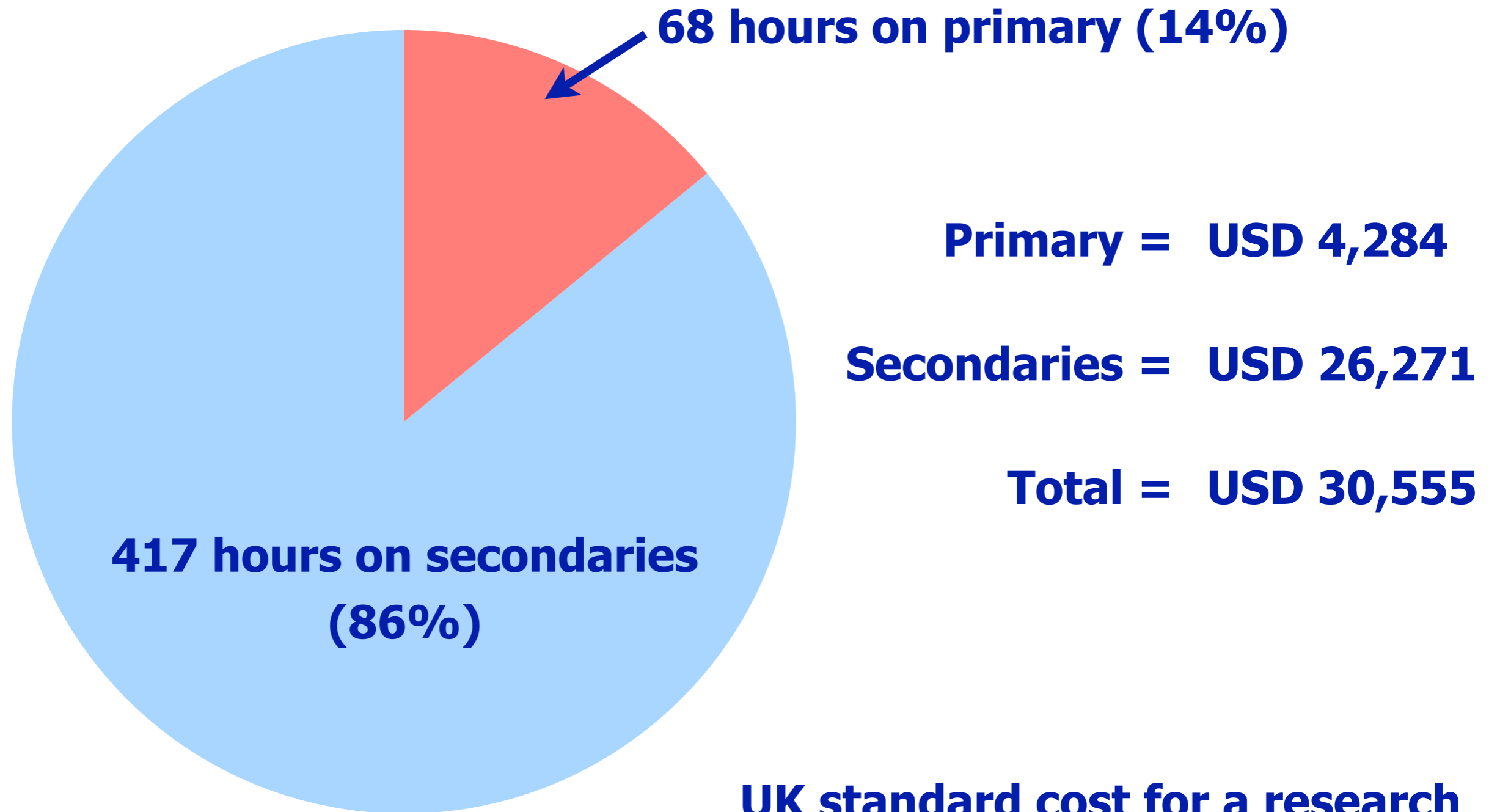
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Primary and secondaries: median times



Primary = USD 4,284

Secondaries = USD 26,271

Total = USD 30,555

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A ratio to remember

**Median ratio of time spent on
primary vs secondary outcomes = 1 : 6**

Summary

- **We spend a lot more time collecting secondary outcome data than primary, sometimes lots, lots more.**
- **Data collection is expensive.**
- **To be worth the effort, collected data need to be available for decision-making. Often it isn't, so why threaten the trial by collecting it in the first place?**

This work is part of



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