Clarivate Cortellis™

Position your trials for success from day one

Leveraging historic trial duration insights to enable data-driven planning

Changes in trial cycle times in recent years are at least partly caused by increasing complexity of trial designs.

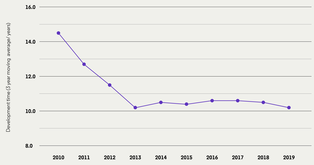
As trial sponsors attempt to do more with less, this complexity brings additional challenges during the protocol writing and patient enrollment periods.

Let's evaluate proprietary data from The Centre for Medicines Research (CMR) International, a wholly owned subsidiary of Clarivate and leading source for biopharma performance metrics and trends, for insight into trial cycle time trends and strategies to improve study planning.

How long is the overall drug development time?*

The data show that overall development time has been decreasing over the last decade to its shortest length in 2019 – **10.2 years in 2019** – but there has been relatively little process improvement over the last seven years.

Development time for new molecular entities first launched onto the world market 2010-2019



*time taken from compound code assigned to first world launch

Is trial phase length changing?

Although the time between protocol approval to first patient enrolled has increased by 16 days from 2014 to 2018, the overall length of clinical trials has:

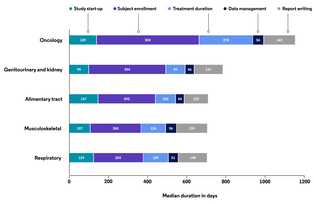
↓	**Phase 1**	**-21%**
↓	**Phase 2**	**-2%**
↑	**Phase 3**	**+8%**

Why are Phase 3 trials getting longer?

Longer patient enrollment periods

It's no surprise that patient enrollment is the longest interval for Phase 3 trials. Since treatment duration is scientifically fixed, there are opportunities to reduce enrollment times by setting defined inclusion/exclusion criteria and stratifying patients who are most likely to respond to treatment.

Median duration of clinical trials completed during 2015-2017 across therapy areas



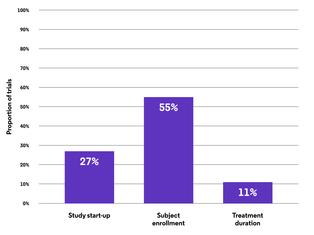
Unexpected protocol amendments

When we look at protocol amendments, the majority are required during subject enrollment and could include modifying the inclusion criteria to capture a broader set of patients.

53% **of trial protocols are amended after initiation**

55% **of amendments occur during the enrollment interval**

Timing of protocol amendments in trials completing enrollment between 2013 and 2017



How can you improve patient enrollment?

Thinking ahead about patient identification and stratification during the study design phase could improve enrollment, reduce the need for amendments and shorten trial timelines:

Use a master protocol, such as basket or umbrella trials.

Identify and stratify patients using biomarkers to include those who are most likely to respond to a treatment.

Choose sites with experience recruiting the chosen patient segment.

Position your trial for success from day one through data driven decision making.

Visit our website to learn more:
clarivate.com/benchmarking

All data used in this analysis was derived from The Centre for Medicines Research 2020 and 2019 Pharmaceutical R&D Factbooks.

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