Comparator Sourcing in Oncology Trials

This is an exciting time for oncology trials, year on year record numbers of therapeutics are launched and the indications for many drugs on the market are increasing rapidly. Immunotherapies and next generation biotherapeutics are being approved for more tumour types and a growing percentage of the late stage oncology pipeline are targeted biologics.

However, with growth comes increased risk. Trials are more complex than ever, with more locations in new geographies and adaptive trials becoming more common. This complexity is affecting trial success rates which are routinely lower than other therapy areas. Post-trial oncology products also experience difficulty entering the market. Immunotherapies and next generation biotherapeutics may be the future of oncology but they are significantly more expensive than older non-specific therapies on the market.

Positive results from health technology assessments, used to inform purchasing decisions, are becoming less and less common in oncology as costs of therapies sky rocket and specificity increases. For a clinical trial to demonstrate the added value of the IMP it is now essential that it is compared to the standard of care rather than a placebo.

This increases costs and therefore risks of a trial but is a necessary component for a novel therapies' success. It is therefore imperative that a clinical trial is well managed and efficient with resources to minimise risks and ensure that the IMP goes to market positively.

There are some encouraging trends, biomarkers and selecting patients from pre-screened pools have increased productivity of trials and lowered costs. Streamlining comparator sourcing is another strategy that can dramatically affect the efficacy of an oncology clinical trial.

Comparator selection is a vital component of a sourcing strategy. Using biosimilars or generics where available can decrease the cost of comparators in a trial by as much as 50%. However, this can be a complicated solution, licensing on biosimilars is dependent on proven pharmaceutical similarity to the reference drug, this can be different between markets potentially affecting the sourcing strategy.

Different sourcing strategies have positives and negatives, local sourcing can be an effective strategy for a small phase I trial in a handful of countries but can be very challenging in a global phase III trial spanning many countries and regulatory bodies. Regulatory complexity is compounded by logistical complexity, working with stakeholders

across the globe to deliver products in a timely manner can be especially challenging. There is not a one fits all solution in comparator sourcing, it is therefore important that extensive research is undertaken to find a range of options. With CSI as a partner you will be receiving gold standard service to de-risk comparator supply in your clinical trial.

CSI safeguards the progress on medicine:

- Extensive expertise supplying a range of oncology products including a strong portfolio of biosimilars and generics from all over the world.
- Excellence in just in time supply for adaptive clinical trials.
- Over 50 years combined experience in clinical trial supply.
- A team of outstanding scientific credentials that thrives on supplying a range of solutions for difficult problems.
- In 2019, we supplied medicines to 98 trials all over the world and worked closely with manufacturers to provide innovative solutions.

For Further information please visit our website: https://www.clinicalservices.eu/

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