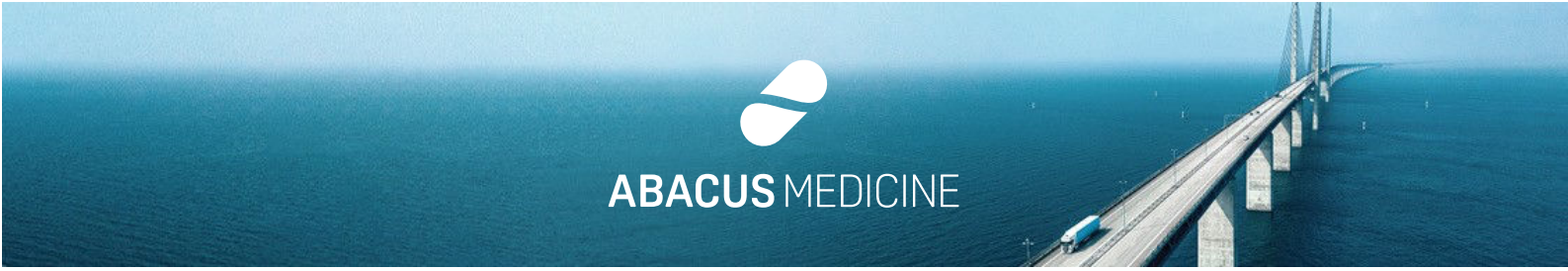


CASE STUDY: WASTAGE

Comparator trial wastage – A Unique Solution

The Opportunity

As clinical trials are increasingly designed to compare new assets with existing gold standard therapies such as Humira, Keytruda and other high cost reference medicines, the cost of the comparator drug budget is becoming a significant proportion of the total trial budget.

With these products typically being sourced at the start of phase II and III trials, the sponsor company can often be left with significant inventory levels that have short expiry dates when a trial is cancelled or aborted. Often, this stock ends up being destroyed.

With patient recruitment problems being a well-documented issue associated with clinical trials, this too may also lead to unplanned build-up of expiry date issues with trial comparator inventory.

The Challenge

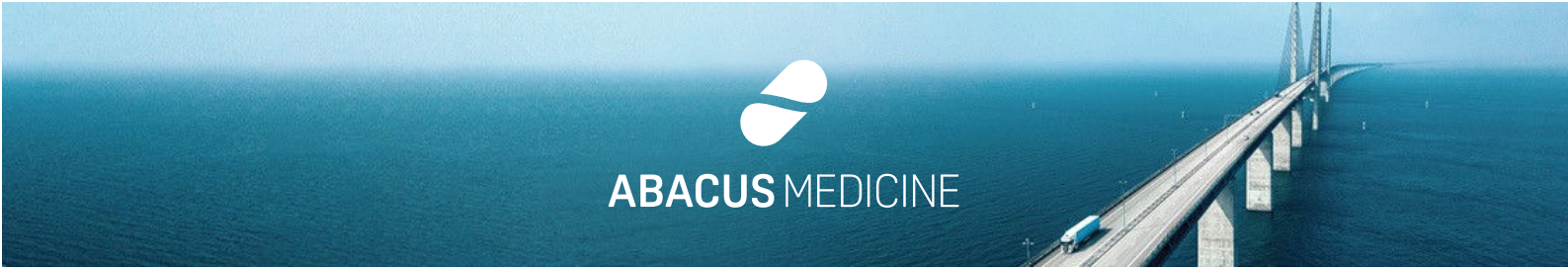
The challenges facing those working in clinical trials are numerous; patient recruitment, adoption of technology and regulatory requirements all leading to spiraling costs. Also, as the cost of modern medicines increases, so does the acquisition cost of the comparator drugs.

Trial information taken from Global Data (Ref 1),from October 2014 to October 2019,shows that >20% of oncology trials were cancelled.

It is difficult to foresee situations that lead to trials being aborted or cancelled and therefore it is not uncommon for companies to be left with stocks of product that are wasted. Add to this the fact that recruitment of patients is notoriously difficult to plan and doesn't go as expected, and again this leads to products not being used and problems with expiry dates.

As comparator drugs are packaged specifically for a clinical trial, once that trial has been cancelled the sponsor company can be facing significant losses including the cost of the required repackaging on top of the comparator costs.

Even when trials are not cancelled, we have received anecdotal information from a top ten pharma company that they experience annual wastage of CTS comparator stock of around 20% every year. The main factor, outside of cancellations, was patient recruitment issues – a global planning problem for all clinical trial programmes.



The Abacus Medicine Solution

By combining the sourcing resources and analytical expertise of Abacus Medicine with the knowledge and expertise of the Clinical Trial Services Team, we can provide a unique service allowing us to procure surplus high-cost clinical trial products from exposed trial sponsors that are at risk of needing to be destroyed.

We can do this, as we hold over 4,500 marketing authorisations and are actively distributing most of the high-value products that are typically used as reference medicines in clinical trials to our healthcare customers throughout Europe.

As with all Abacus Medicine services, products are handled to international quality standards and are sent to our state-of-the-art production facility in Hungary. After being put through a full quality check, they are re-packaged and sold to our customer base of hospitals and pharmacists in the major European countries.

The Results

One of our biotechnology clients had to cancel a clinical trial and as a result, was planning to write-off all the clinical trial stock that had been sourced and repackaged. By utilising our unique capabilities, we were able to deliver a solution to procure over 300 packs of this surplus product that the client was planning to write-off and re-sell it to our healthcare customers.

The Benefits

The client was able to recoup a value of >€400,000, which would have otherwise been lost, as a result of using our Clinical Trial Services and could invest it into future development programs.