CASE STUDY

AstraZeneca - How optimization during trial design helps reduce drug waste

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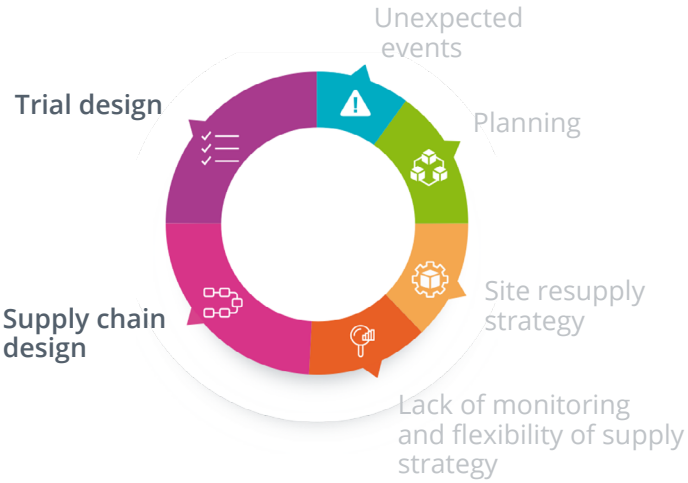
Clinical trials are the core of innovation in healthcare, and at the forefront of drug development all in an effort to save future lives. In order for clinical trials to be successful, patients must be recruited and treated with investigational drugs. Although ensuring patient dispensing with such potential randomness implies a high margin of supply, it is often overlooked that this waste can be controlled and reduced without impacting patient safety.

On average, 70% of drugs supplied in clinical trials are wasted, according to industry surveys and analysis, not only creating a financial burden, but also unnecessarily depleting finite resources. It is clear that maintaining a patient-centric approach while also streamlining waste is a challenge, but has also become a priority for biopharma companies, rather than a choice.

In this case study, you will discover more about:

- The most impactful drivers of waste
- AstraZeneca's journey
- The Trial Design Thinking Process using a concrete example:
  - Prediction of the randomization visit
  - Only cover the next potential titration
  - Optimization of kit design

Most impactful drivers of waste



50% of waste depends on the design of the clinical trial and its supply chain

Through N-SIDE's experience on thousands of trials, our experts have identified the main drivers of this need for excess kits and their impact on the waste. Although the trial and supply chain designs are not the most accessible drivers of waste to tackle, they represent an average of 50% of the sources of waste. This case study will show how good collaboration and data-driven decisions can drastically reduce waste without impacting the patient's safety.

AstraZeneca's journey

At AstraZeneca, a lot has been done in recent years to implement an agile structure that can face today's clinical supply chain challenges. One step they took towards this goal was to introduce a new role in their clinical supply chain department.

Recently, a new role was added to the team to create a bridge between the creation of a new study and the operational activities once the study starts: the Study Design Specialist. This role focuses solely on optimizing the trial design based on concrete data-driven decisions. It allows them to work on reducing waste, and reducing the workload. This new structure also has the benefit to steer them towards their carbon neutrality ambitions.

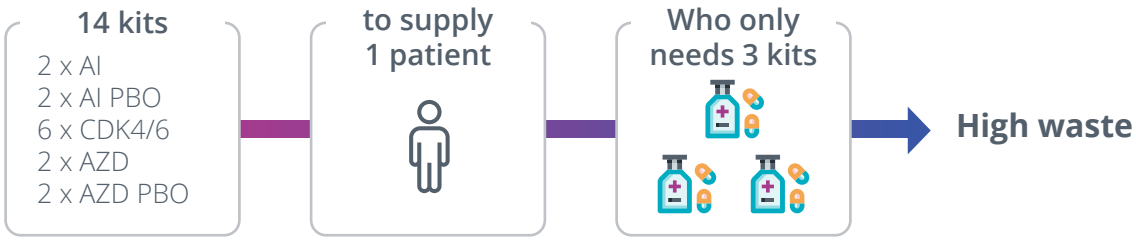
Case study: Trial Design Thinking Process applied to an oncology trial

Below are three examples of relevant scenarios that the Study Design Specialist at AstraZeneca suggested together with N-SIDE in order to reduce the waste and cost of their trial while keeping the patient's safety a key priority.

These examples illustrate the joint efforts made on an oncology study where various characteristics of the trial were challenged and discussed with the different departments involved.

1 Prediction of the randomization visit

Challenge: This trial had numerous treatment options and had to maintain a proper standard of care across all patient groups.



Context

Following a "traditional" buffer strategy to cover the patient's randomization, 14 kits were shipped to the sites to supply 1 patient where only 3 kits were actually needed. This led to a globally high level of waste.

Challenging Trial Design

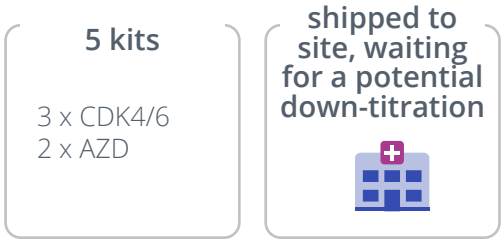
With this configuration, massive waste is generated by the buffer levels. Reducing the uncertainty of randomization is the major challenge to overcome to reduce the waste. By using an extended screening period, all information on the treatment could be collected, and the kits shipped accordingly, which in turn, would drastically reduce the potential waste.

By changing the IRT configuration and increasing the minimum screening period to 14 days, AstraZeneca successfully implemented the prediction at screening. Only the known prior treatment would be shipped to the site by taking into consideration patient Standard of Care *(SOC)* tracked at screening, reducing site inventories considerably. It also allowed to ship enough drug to cover consecutive randomizations in cases where multiple patients were screened at the same time.

This led to a **cost reduction** of 7% and **decreased the risk** of missed dispensing for the patients.

2 Only cover the next potential titration

Challenge: In this trial, patients could down-titrate at any time. They were three dose levels and patients would get a different kit dispensed depending on their dose.



Context

Once randomized, each patient receives three treatments; titrations are allowed for two of them. In the initial design, all doses are sent on-site as buffers to ensure a safe titration path.

Challenging Trial Design

Based on the protocol, patients could only down-titrate one dose level per visit. Therefore, the shipment rules could be adjusted to only ship the kit for the 1st dose reduction at the randomization. The next dose would be shipped only if patients down-titrated the first time.

This new shipping strategy would reduce the high level of buffers needed to cover the titrations. The results show a **waste reduction of 15%** of packages to produce and **cost savings of 16%**.

3 Optimization of kit design

Context

For one of the most expensive SOC, 3 different kit types were initially considered to cover the patients' dispensing: one for each dose level (50, 100, and 150mg).

Challenging Trial Design

Having multiple kit types considerably increases the waste, while the different dose levels could be dispensed with a combination of 50mg kit types. Although this solution would require a change in the kit design, it would significantly reduce the required buffers at sites and depots, hence leading to a decrease in total production needs.

In this case, only using a combination of 50mg kit type couldn't be implemented for patient-centricity reasons. Indeed, for a dose of 150mg, the patient would have been required to take more than six pills a day just for this kit. Therefore, the three different kit types were kept.

Global impact

By challenging the **trial design** and involving the clinical supplies department in the study and supply chain design, significant results in terms of waste reduction and cost savings were successfully implemented by AstraZeneca. Over the trial lifecycle, this will bring more visibility on real patient demand and supply needs, significantly reduce the workload of the supply team, and accelerate clinical timelines, overall resulting in a more supply and environmental-friendly clinical trial.

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