IDDI
DATA WITH PURPOSE

CASE STUDY

Optimizing The Drug Supply Strategy

Study Description

- Phase II Study
- Efficacy assessment of a new drug in combination with an antibody in patients with advanced triple negative breast cancer

Indication

Breast cancer

Patient population

88 adult subjects

Regions

North America

Situation

- Expensive drug to manufacture
- Different compositions for both placebo and active drugs:
  - 5 mg vials
  - 3 mg vials
  - 2 mg vials
- In case of an event, drug dose reduction occurs
- Difficult to predict 3 mg and 2 mg drug allocations
- Usage of central pharmacies

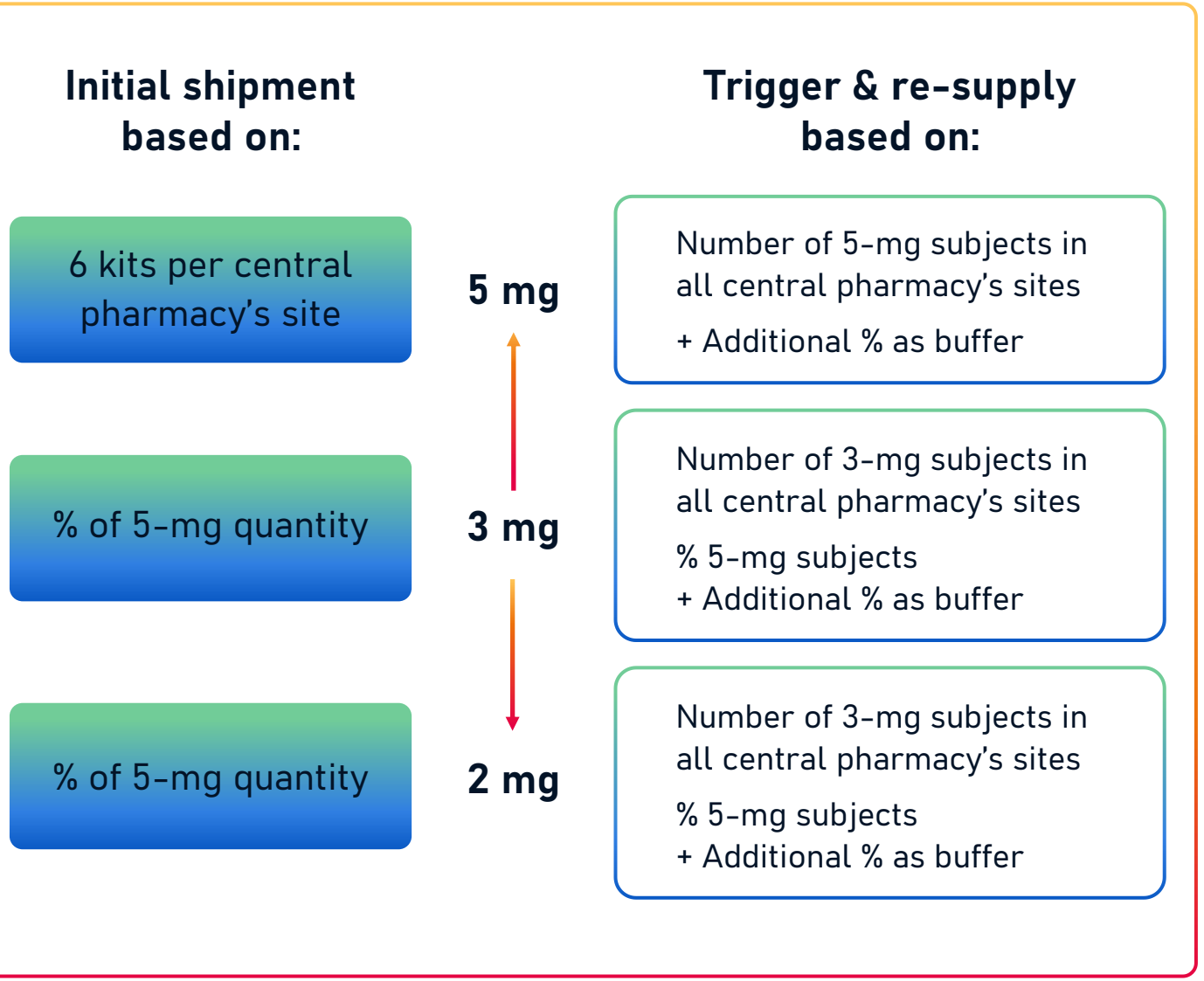
Sponsor request

Optimize the drug delivery (limit the quantity of shipped vials yet assure sufficient vials are on site)

Solution

IDDI team's answer:

- The IDDI RTSM team proposed a predictive drug supply model
- All % 's advised by the IDDI Biostatistician team
- All % 's can be adjusted as needed during course of trial (based of history)



Solution Details

Predictive drug supply model

Initial shipment

- Knowing that all patients would start their medication using 5 mg vials, it was decided to have 6 kits per site. If the central pharmacy was serving three sites, then we would have an initial shipment of 18 kits.
- Then we decided to have a percentage of the 5 mg quantity for the 3 mg drugs and another for the 2 mg vials.

Trigger & resupply quantities :

- Definitions:
  - Resupply will be triggered when there are not sufficient vials on-site for the next 2 vial allocations for the current active patients at the Central Pharmacy's sites.
  - The resupply quantity is the number of vials that need to be shipped to assure enough vials are on-site for the next 4 allocations.
- For 5 mg vials, we based our calculation on the number of active subjects currently using 5 mg vials. For the resupply quantity, we added a percentage as a buffer to make sure that we had sufficient drugs available in all cases.
- For 3 mg vials, we based our calculation on the number of active subjects currently using 3 mg vials, but we also considered a percentage of the 5 mg subjects that would need to have a slower dosage and move from 5 to 3 mg. Again, adding an additional buffer for the resupply.
- For 2 mg vials, we took a similar approach now considering a percentage of the 3 mg subjects because some of them might go to 2 mg.

Results

IDDI has successfully delivered

Proposing a Predictive Drug Supply Model enabled the Sponsor to optimize the drug delivery

Contact Us

Whether you need assistance with your clinical strategy, study design, clinical data management, or biostatistical analysis, IDDI's experts are here to help.

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We deliver uncompromising excellence in biostatistics, strategic consulting, clinical data management, IDMCs, and supporting eClinical technologies, because when every data point represents a patient, perfection is the only option.