



ADDING A STRATIFICATION FACTOR DURING THE STUDY

IDDI CASE STUDY

STUDY DESCRIPTION



Phase III study randomized study comparing 2 drugs (Drug1 and Drug2) following chemotherapy in patients with newly diagnosed FLT3-mutated acute myeloid leukemia



INDICATION

PATIENT POPULATION

REGIONS

Acute Myeloid Leukemia

Large Sample

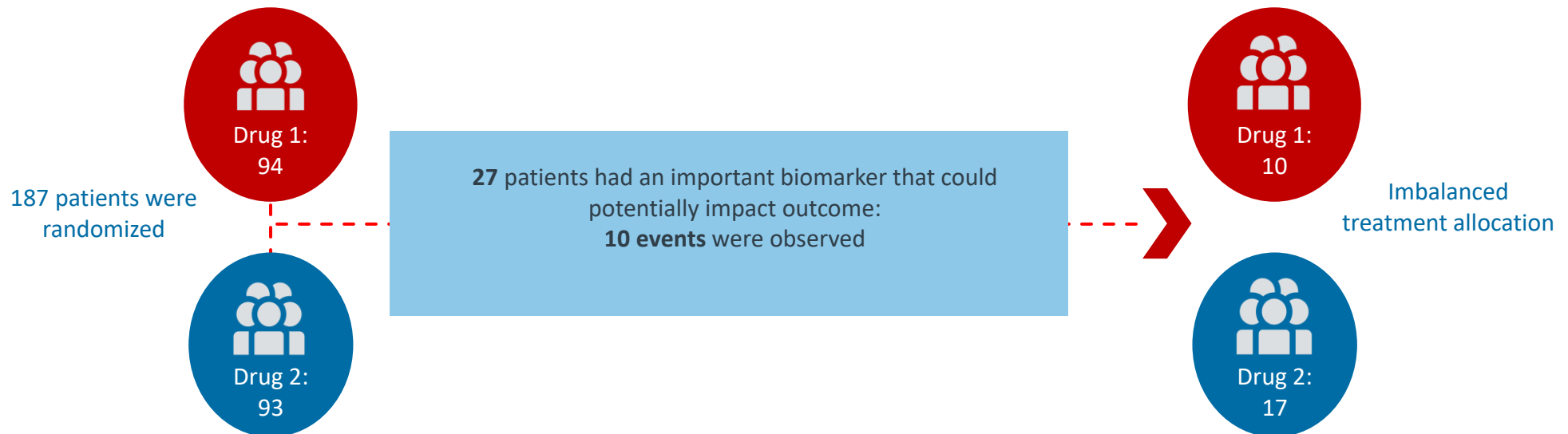
North America

SITUATION

Randomized study using a 1:1 minimization algorithm based on 6 stratification factors

Early result review and observation:

- 187 patients randomized (94/drug1 : 93/drug2)
- 27 patients identified with an important biomarker that could potentially impact the outcome
 - 10 events were observed among the 27 patients
 - Imbalance treatment allocation for those patients (10/drug1 : 17/drug2)



Sponsor Request:

Integrate that biomarker as a stratification factor (replace or add stratification factor)

SOLUTION

- IDDI Biostatisticians advised to add this important biomarker as a stratification factor
- RTSM team imported the collected biomarker data for existing patients in the RTSM platform

RESULTS

IDDI has successfully delivered

Adding a stratification factor & importing the collected biomarker data for existing patients allowed the Sponsor to **reach overall balance amongst the 2 arms for these 7 stratification factors**

SOLUTION DETAIL (1)

Initially 6 stratification factors

Initial situation

	Strat1	Strat2	Strat3	Strat4	Strat5	Strat6	Arm
Subject 1	1	0	1	1	0	0	Drug 1
Subject 2	0	1	1	0	1	0	Drug 2
Subject 3	1	1	0	1	0	1	Drug 1
Subject 4	1	0	1	0	0	0	Drug 1
Subject 5	0	1	0	0	1	0	Drug 2
Subject 6	0	0	0	1	0	1	Drug 1
Subject 7	1	0	1	0	1	0	Drug 2
Subject 8	0	1	0	1	1	0	Drug 2
Subject 9	0	0	1	1	0	1	Drug 1
Subject 10	1	0	0	1	1	0	Drug 2
Subject 11	0	1	0	0	0	0	Drug 1
...
Subject 187	0	1	0	1	0	1	Drug 1

SOLUTION DETAIL (2)

Adding a stratification factor during the study

- Adding a new stratification factor results in having a second round of randomization not considering the information from the previous Strat.
⇒ No overall balance: the balance will only be calculated for the upcoming next randomized patients

Adding Stratification Factor (no overall balance)

	Strat1	Strat2	Strat3	Strat4	Strat5	Strat6	Strat7	Arm
Subject 1	1	0	1	1	0	0		Drug 1
Subject 2	0	1	1	0	1	0		Drug 2
Subject 3	1	1	0	1	0	1		Drug 1
Subject 4	1	0	1	0	0	0		Drug 1
Subject 5	0	1	0	0	1	0		Drug 2
Subject 6	0	0	0	1	0	1		Drug 1
Subject 7	1	0	1	0	1	0		Drug 2
Subject 8	0	1	0	1	1	0		Drug 2
Subject 9	0	0	1	1	0	1		Drug 1
Subject 10	1	0	0	1	1	0		Drug 2
Subject 11	0	1	0	0	0	0		Drug 1
...
Subject 187	0	1	0	1	0	1		Drug 1
Next randomized 1	1	1	0	1	0	1	0	Drug 1
Next randomized 2	1	0	0	1	1	0	1	Drug 2

SOLUTIONS (3)

Importing the collected biomarker data for existing patients

- Importing the collected biomarker data for the previous subjects made it possible for the next randomization to consider all the stratification factors.
⇒ Overall global balance for all the subjects was reached as more and more patients got randomized through the minimization process

Importing collected data for overall balance

	Strat1	Strat2	Strat3	Strat4	Strat5	Strat6	Strat7	Arm
Subject 1	1	0	1	1	0	0	1	Drug 1
Subject 2	0	1	1	0	1	0	1	Drug 2
Subject 3	1	1	0	1	0	1	0	Drug 1
Subject 4	1	0	1	0	0	0	1	Drug 1
Subject 5	0	1	0	0	1	0	0	Drug 2
Subject 6	0	0	0	1	0	1	0	Drug 1
Subject 7	1	0	1	0	1	0	1	Drug 2
Subject 8	0	1	0	1	1	0	0	Drug 2
Subject 9	0	0	1	1	0	1	1	Drug 1
Subject 10	1	0	0	1	1	0	0	Drug 2
Subject 11	0	1	0	0	0	0	1	Drug 1
...
Subject 187	0	1	0	1	0	1	0	Drug 1
Next randomized 1	1	1	0	1	0	1	0	Drug 2
Next randomized 2	1	0	0	1	1	0	1	Drug 1

CONTACT US



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www.IDDI.com



+32 (0) 10 61 44 44 | +1 984 227 8599



info@iddi.com

ABOUT IDDI

- International Drug Development Institute (IDDI) is an expert organization in biostatistical and integrated eClinical services that is committed to assisting pharmaceutical, biotech, medical devices, and Cooperative Groups in several disease areas, with a special focus on oncology and ophthalmology.
- IDDI optimizes the clinical development of drugs, biologics and devices thanks to proven statistical expertise and operational excellence.
- Founded in 1991, IDDI has offices in Belgium, Boston (MA) and Raleigh (NC).

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