

RANDOMIZATION & TREATMENT ALLOCATION SYSTEM - RTSM

The Only Biostatistics-driven
RTSM



**FASTER DEPLOYMENT OF
YOUR STUDIES**

By combining IDDI's statistical expertise with CLARIO's RTSM know-how, we ensure your studies are configured in the most reliable & efficient way, securing your trial integrity.

- Supports all types of randomization scenarios (Fixed, dynamic, multi-stage, adaptive)
- Configurable and customizable
- Supports all protocol designs
- Support for mid-study changes in days and with no downtime
- Fast implementation of protocol amendments
- Fast Delivery: 4 < 7 weeks
- Direct integration with IDDI EDC ID-base (Marvin) and Rave (Medidata)
- Interoperable with any third-party eClinical systems
- Supports complex trial supply algorithms
- Flexible reporting options

CLARIO.

THE ONLY BIOSTATISTICS-DRIVEN RTSM

Our statisticians are involved from start to end to provide the most appropriate randomization methodology and follow up.



STUDY DESIGN

The biostatistician:

- Defines the randomization method in the protocol
- Defines the stratification factors in the study protocol, with a medical expert
- Runs random simulations to see the distribution of the subjects per stratification factor



STUDY SET-UP

- Randomization algorithm re-validation
 - Ensures correct implementation of the randomization based on the protocol
- Drug kit allocation validation
 - Ensures correct allocation of drug/dose based on the assigned treatment group & the defined schedule in the protocol



STUDY FOLLOW-UP

- Randomization balance check
- Drug kit allocation accuracy check