



FlexRandomizer[®]

Easy Randomization in Real Time

Priyadarshan Shinde, Cytel
Mangesh Kulkarni, Cytel

PhUSE 2017, Edinburgh

Agenda

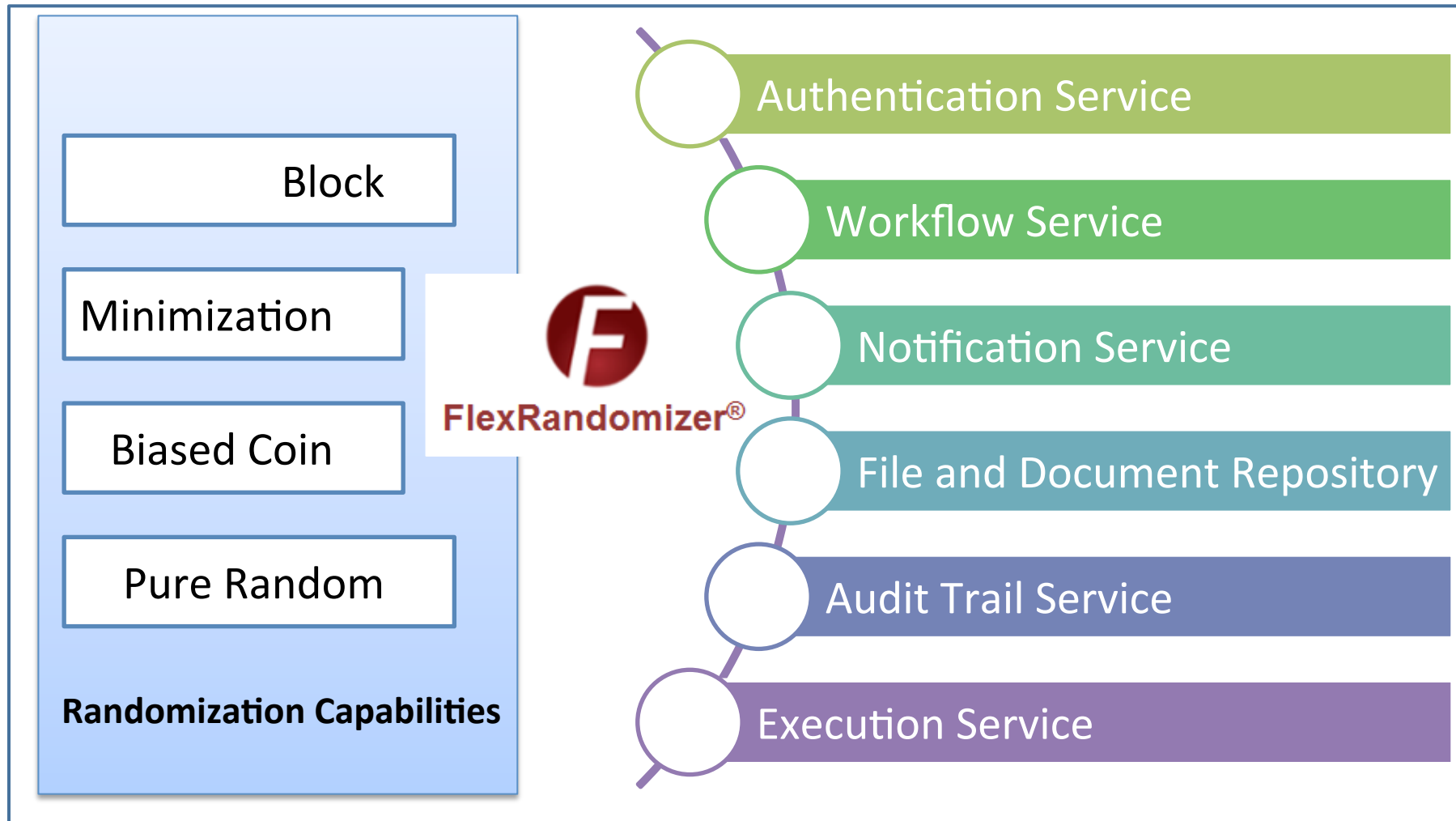
- Introduction
- System Overview
- Live Demo
- Summary

Introduction



FlexRandomizer[®] is a state-of-the-art **enterprise web** based **application**, which facilitates the randomization process in clinical trials. It has capability to **integrate** and communicate with **external systems** including those of the electronic data capture (**EDC**) and interactive response system (**ixRS**)

FlexRandomizer[®] Platform



Authentication: Role Based Access

FlexRandomizer Administrator

- **Configure** application settings
- Generate **system** level **audit trail** report
- **Assign** protocol owner and administrator **roles**

Protocol Owner

- **Define** protocol in the system
- Uploads protocol **documents**
- **Assign** randomization generator and QC **roles**
- Generate **protocol** level **audit trail** report

Authentication: Role Based Access CONTD.

Randomization Generator

- Configure **randomization** specifications
- Configure **kit** specifications
- Define list **templates**
- **Assign** generated lists for QC

QC

- Perform **quality checks** for assigned lists.

Walk-through

Lets walk-through following activities inconsideration with sample subject randomization

- Protocol Creation
- Randomization Specification Configuration
- List Template Configuration
- List Generation & Assignment for QC
- QC Approval/Rejection
- Different Dashboards
- Audit Trail Reports

Randomization Request

Subject randomization request for a Protocol

- Protocol ID:** DS453-235
- Treatment Arms:** XBA-VIA, Placebo
- Treatment Ratio:** 1:1
- Stratification Factor:** 2 Stratification factors
 - Age (<18 Years , >=18 Years)
 - Gender (Male, Female)
- Block Sizes:** 4, 8
- Mask ID:** Mask ID is required
 - **Starting** with “M”
 - Followed by **4 Digits**
 - **Range** – M0001 to M9999
- Total # of Randomizations :** 960

Output Requirements

Output File Specifications

- Generate **three** randomization lists
 1. **Master List** – Include Stratum, Mask ID, Randomization Number, Block Number, Treatment Code and Treatment Name
 2. **Mask ID List** - Only include **Mask ID** and **Randomization Number**
 3. **Mask ID Treatment List** - Only include **Mask ID** and **Treatment Code**
- All files should be in **CSV** file format

Output Requirements CONTD.

File Naming Convention

<*Protocol ID*>-<*List Name*>-<*Mode*>-<*Version*>-<*Date of Generation*>.csv

Examples

1. DS453-235-MASKTER-RAND-LIST-DUMMY-V1.0-201701XX.csv
2. DS453-235-MASKID-LIST-DUMMY-V1.0-201701XX.csv
3. DS453-235-MASKID-TREATMENT-LIST-DUMMY-V1.0-201701XX.csv

Example List

Stratum	Mask_ID	Rand_Num	Block_Num	Treatment	Trt_Name
<18 Years_Male	Mxxxx	nnnn	nnn	Placebo	Placebo
>=18 Years_Female	Mxxxx	nnnn	nnn	XBA-VIA	XBAVIA



FlexRandomizer®

Live Demo

Summary

FlexRandomizer[®] provides the following benefits:

- **Validated** standard **software** system.
- Provides a **platform** that can standardize the **workflow**
- Provides **centralized view** to the study stakeholders to view progress
- Addresses **regulatory concerns** of tracking trial changes, operational bias, and auditability.
- Provides **wide range** of **options** for list configuration and **extraction**.
- Ability to **connect** to **external systems**.



SHAPING THE FUTURE OF DRUG DEVELOPMENT



Thank you

Priyadarshan Shinde

Priyadarshan.shinde@cytel.com

Mangesh Kulkarni

Mangesh.Kulkarni@cytel.com