

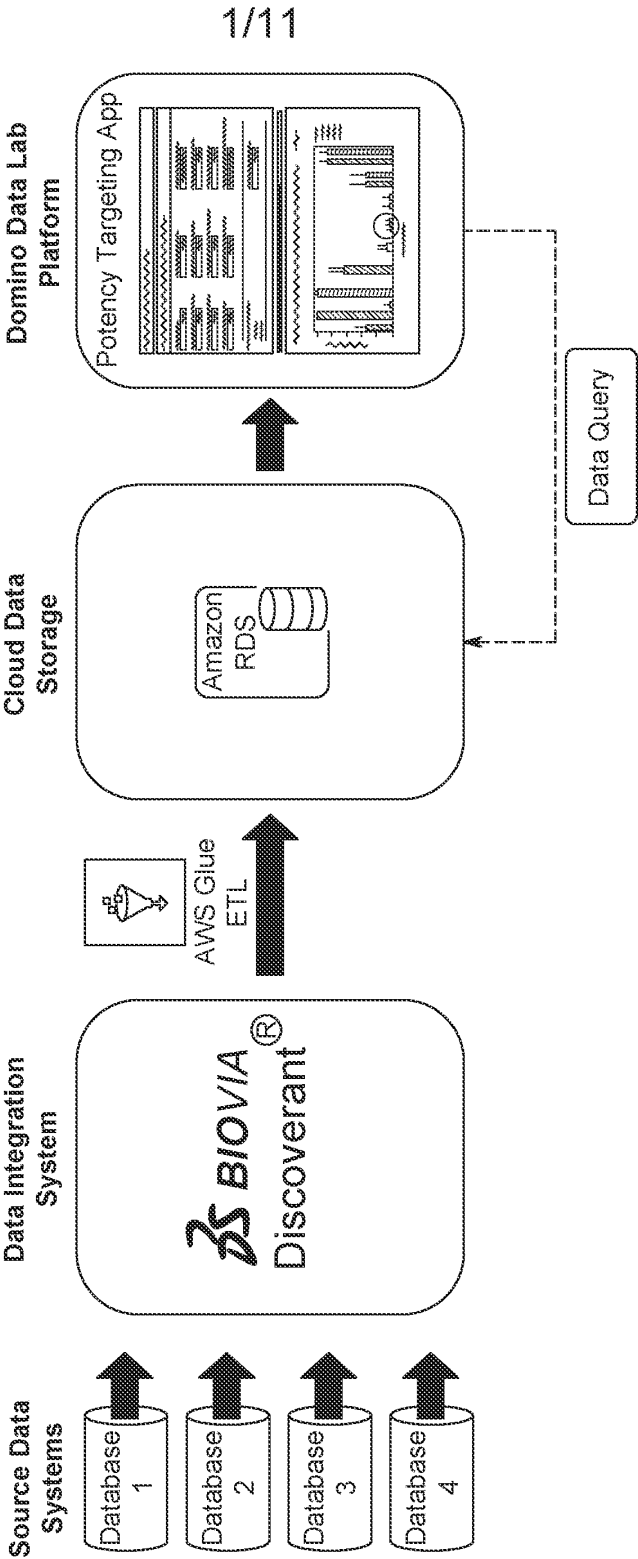


FIG. 1

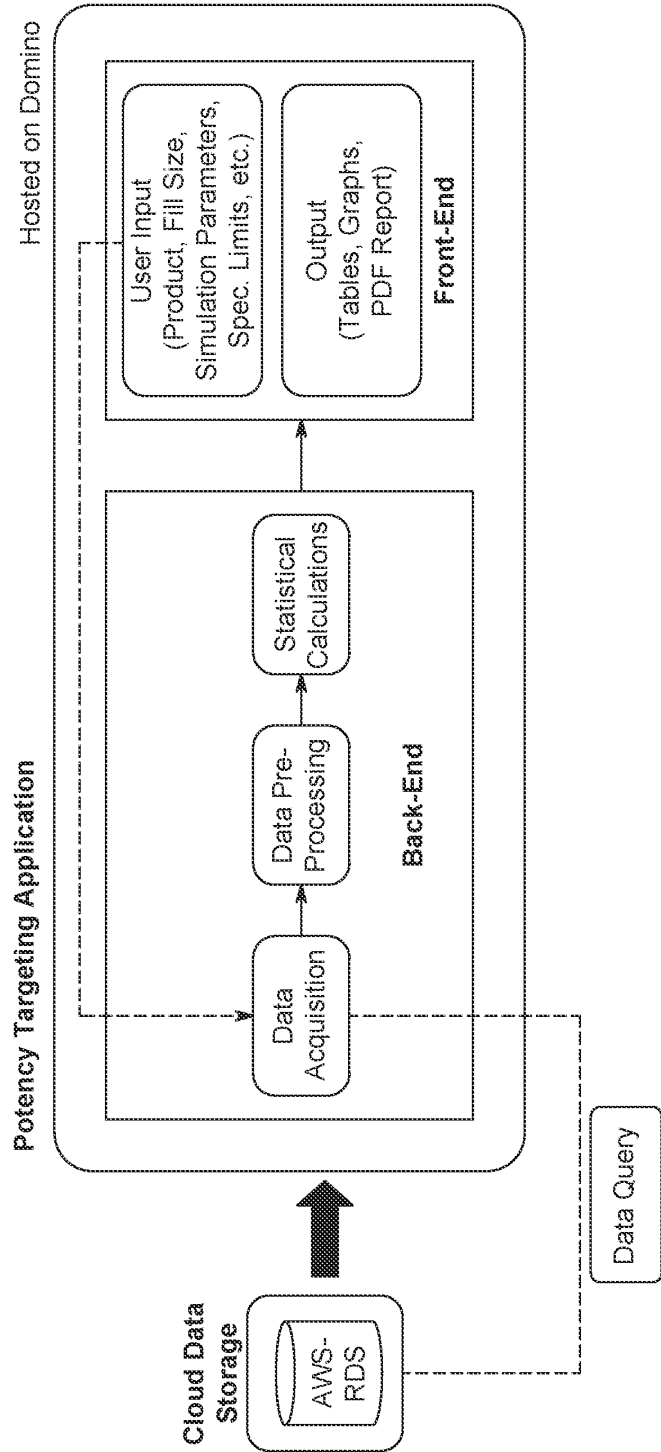


FIG. 2

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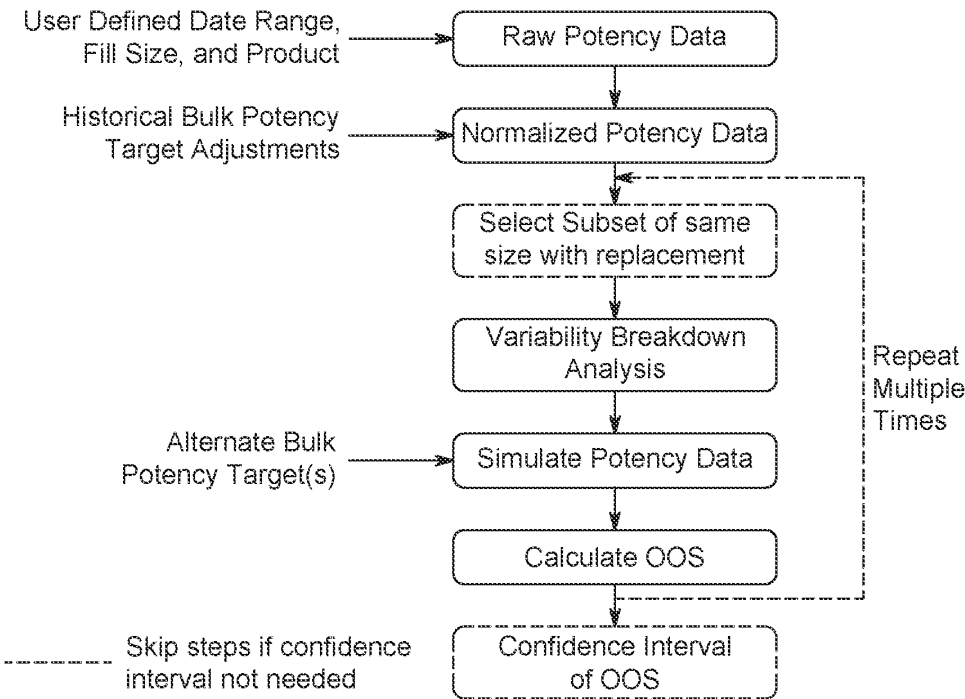


FIG. 3

Potency Targeting Applicationv1.0

Data Selection

Data Scope

Select Product Used for Analysis

- ☒ Drug A
- ☐ Drug B

■ Step Complete: Data Acquisition X

Data has been acquired for the selected product: Drug A

Online Data Source

- ☒ Discoverant
- ☐ None
- ☐ Other

Offline Data Source

- ☐ Yes
- ☒ No

Submit

Download Combined Data (Online & Offline)

FIG. 4

Step Complete: Data Scope Filter X

Data has been filtered for the selected product: Drug A; fill-size: Fill Size 1, start-date: 2022-01-01, end-date: 2023-04-01

Data Filter

Select Fill Size

☒ Fill Size#1

☐ Fill Size#2

☐ Fill Size#3

☐ Fill Size#4

☐ Fill Size#5

Comment Box

Rationale and comments on batch exclusion belongs here.

Select Start Date

01/01/2022

Select End Date

04/01/2023

Select Batch

Batches ▼

☒ Batch 1

☒ Batch 2

☒ Batch 3

☒ Batch 4

☒ Batch 5

☒ Batch 6

☒ Batch 7

☒ Batch 8

☒ Batch 9

☒ Batch 10

☒ Batch 11

☒ Batch 12

☒ Batch 13

☒ Batch 14

☒ Batch 15

☒ Batch 16

☒ Batch 17

Submit

Download Filtered Data

FIG. 5

Step Complete: Input Bulk Potency Targets X

Data Normalization

Input Bulk Potency Targets

Insert Row (Top)

Insert Row (Bottom)

	Bulk Manufacturing Data (YYYY-MM-DD)	Bulk Potency Target (IU/mL)
X	Date #1	123
X	Date #2	120
X	Date #3	118

Normalized potency values have been calculated for the selected batches based on the user input of bulk potency targets.

Submit

Download Bulk Potency Target Table

Download Normalized Data

FIG. 6

Evaluation of Alternate Potency Targets

OOS Risk Estimation (Simulation) Parameter Settings

Number of Vials

10

Individual Lower Limit (IU/mL)

87

Number of Simulated Batches

50000

Batch Validity Upper Limit

6.4

Current Target (IU/mL) ⓘ

118

Individual Upper Limit (IU/mL)

125

Number of Bootstrapped Datasets ⓘ

1000

Batch Validity Upper limit Units

CV % x ▼

Alternate Target (IU/mL)

106, 110, 115, 118, 123

Mean Lower limit (IU/mL)

103

Confidence Level (%)

95

Specify Assay Uncertainty (CV%) ⓘ

Confidence Interval

OFF / ON

Simulation Seed Num. ⓘ

1234

Submit

Cancel Running Simulation

100.0%

FIG. 7

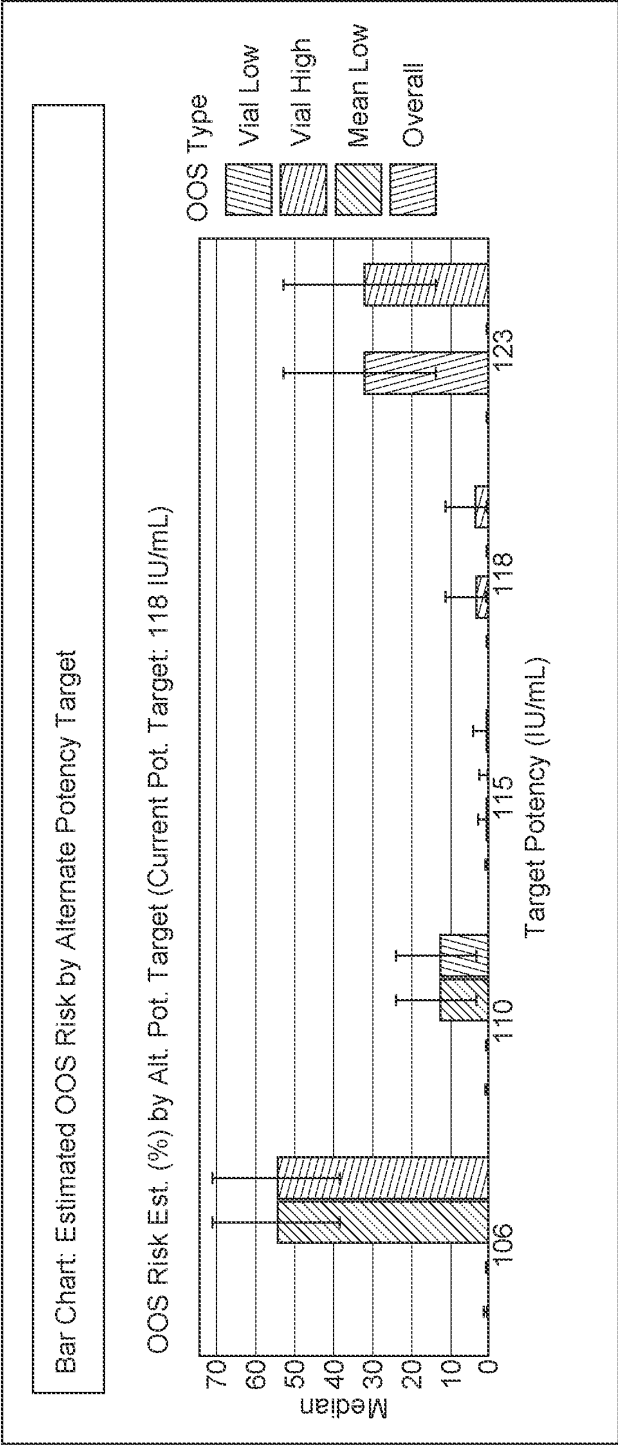


FIG. 8

Evaluation of Alternate Potency Targets

OOS Risk Estimation (Simulation) Parameter Settings

Number of Vials

10

Individual Lower Limit (IU/mL)

87

Number of Simulated Batches

50000

Batch Validity Upper Limit

6.4

Current Target (IU/mL) ⓘ

118

Individual Upper Limit (IU/mL)

125

Number of Bootstrapped Datasets ⓘ

1000

Batch Validity Upper limit Units

CV % x ▼

Alternate Target (IU/mL)

106, 110, 115, 118, 123

Mean Lower limit (IU/mL)

103

Confidence Level (%)

95

Specify Assay Uncertainty (CV%) ⓘ

2

Confidence Interval

OFF / ON

Simulation Seed Num. ⓘ

1234

Submit

100%

Cancel Running Simulation

FIG. 9

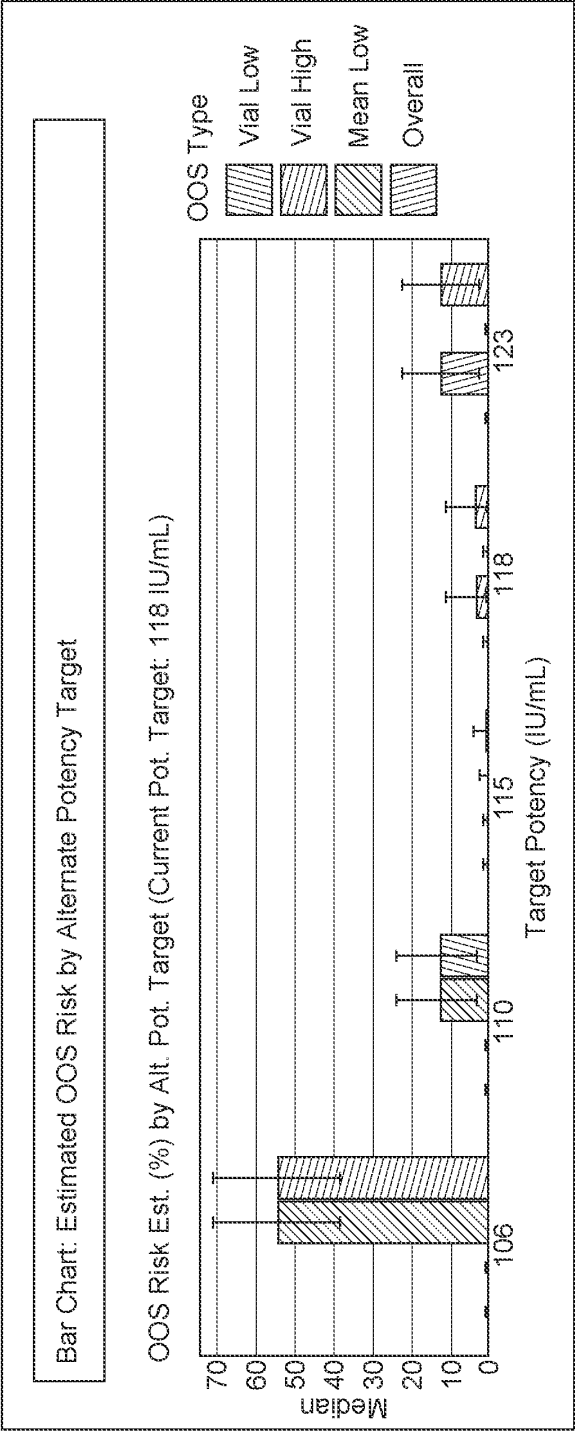


FIG. 10

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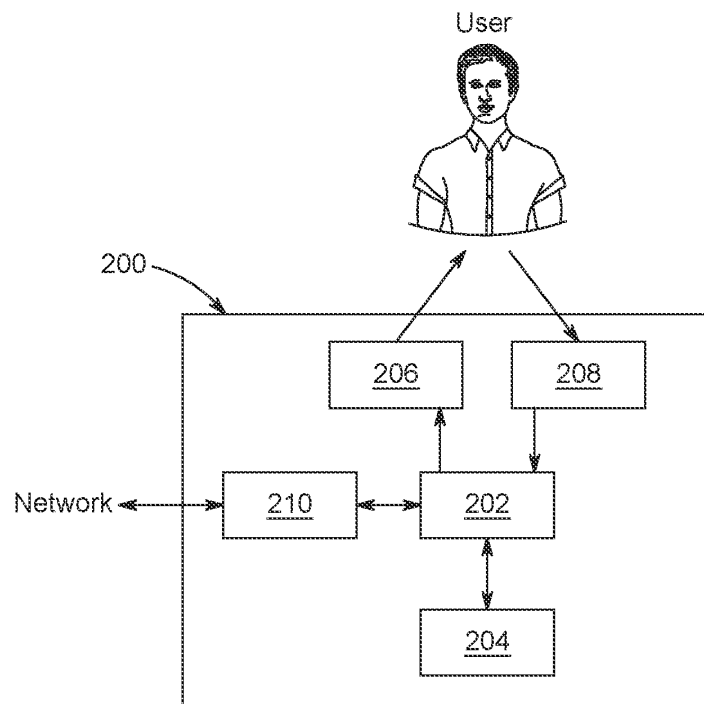


FIG. 11