

Visualisations interactives de données au service de la prise de décision sur les études cliniques de phase précoce en oncologie

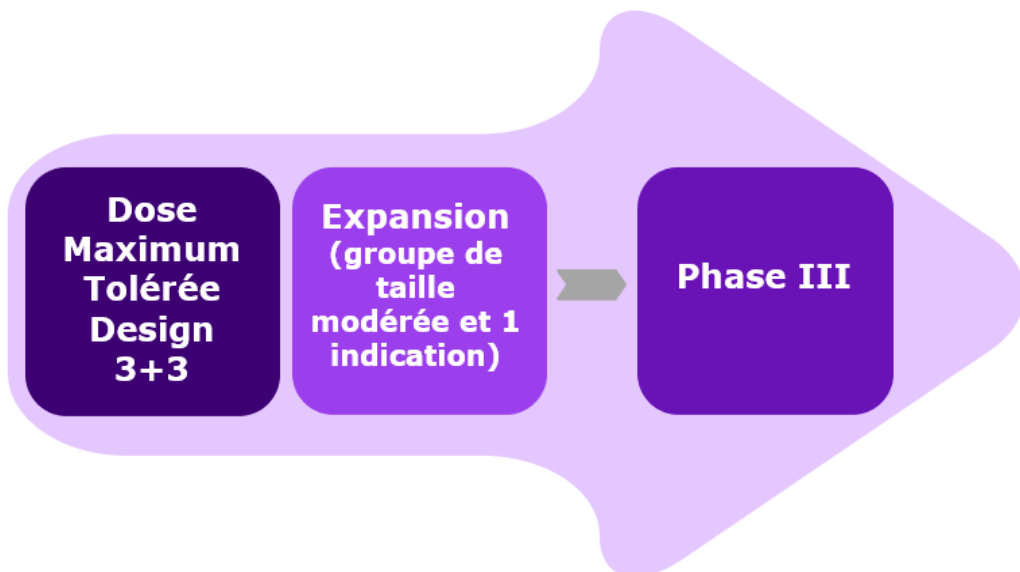
Interactive DEcision Output (IDEO)

Charlotte Cheinin → *ma vision personnelle d'un succès d'équipe*

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Sanofi, Clinical Science Operations, Biostatistics & Programming

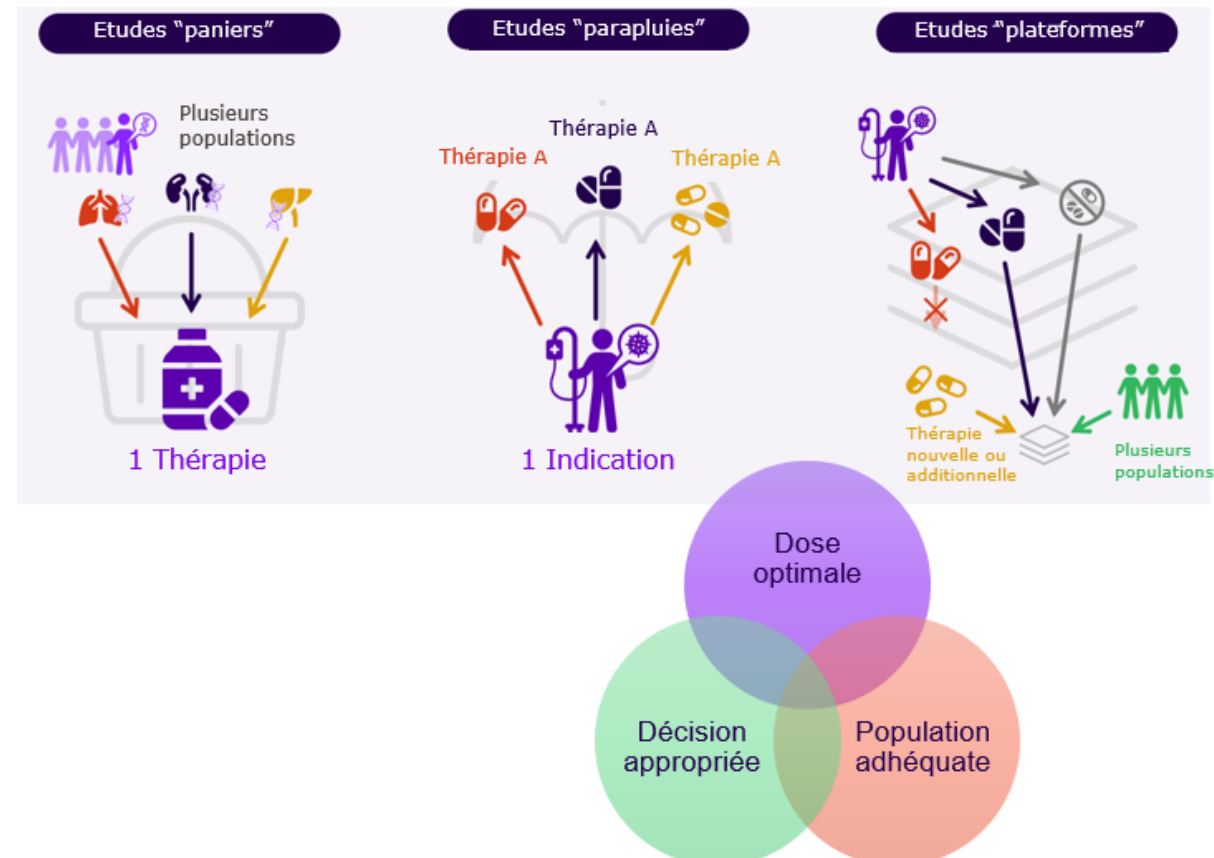
Evolution des plans de développement d'études cliniques

Approche traditionnelle



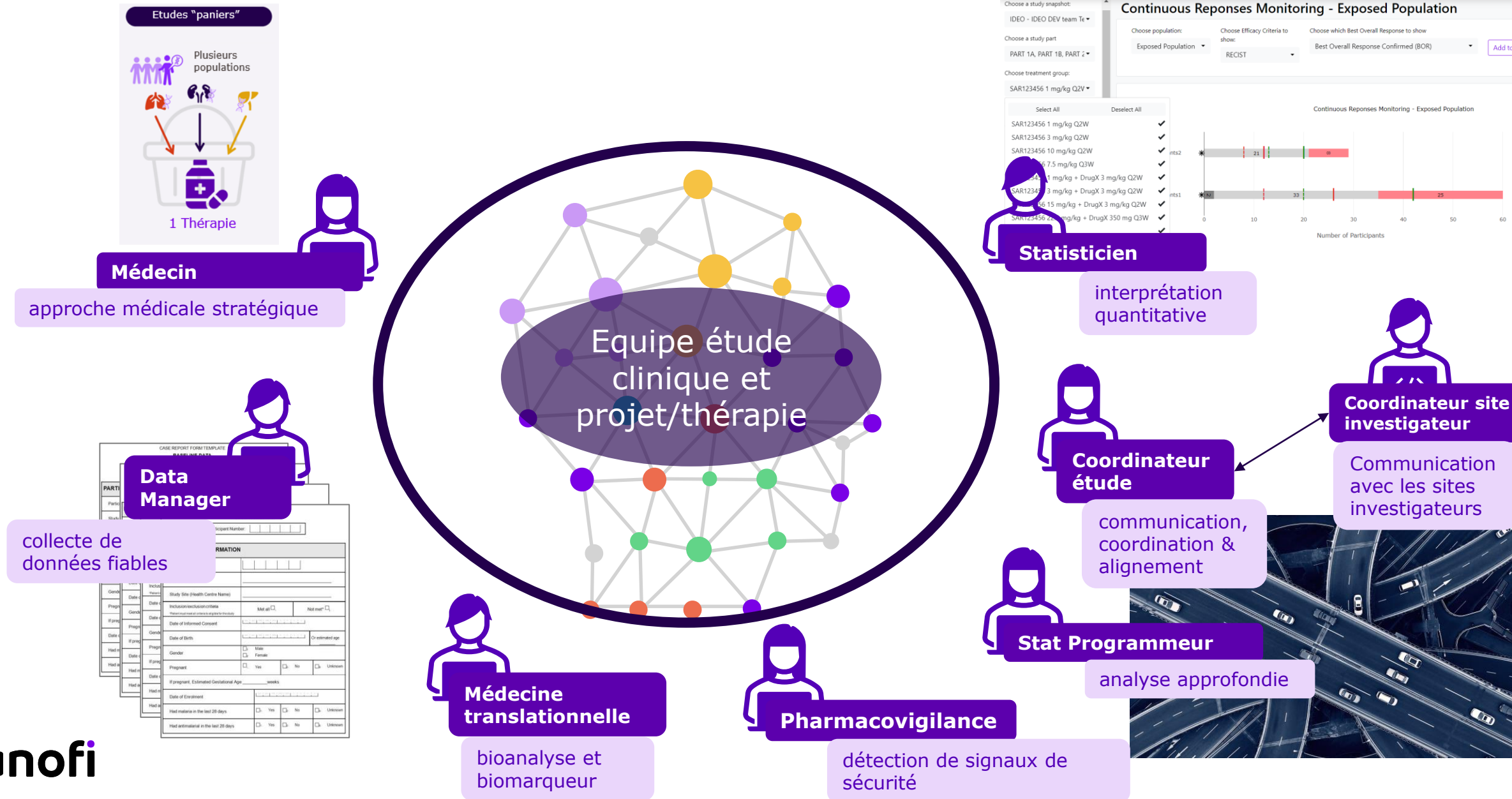
Séquentielle

Approche succès/échec rapide



Plan de développement plus complexe, couple avec des méthodes statistiques innovantes afin de mieux adresser les questions scientifiques et accélérer la prise de décision

Prise de décision : une collaboration pluridisciplinaire

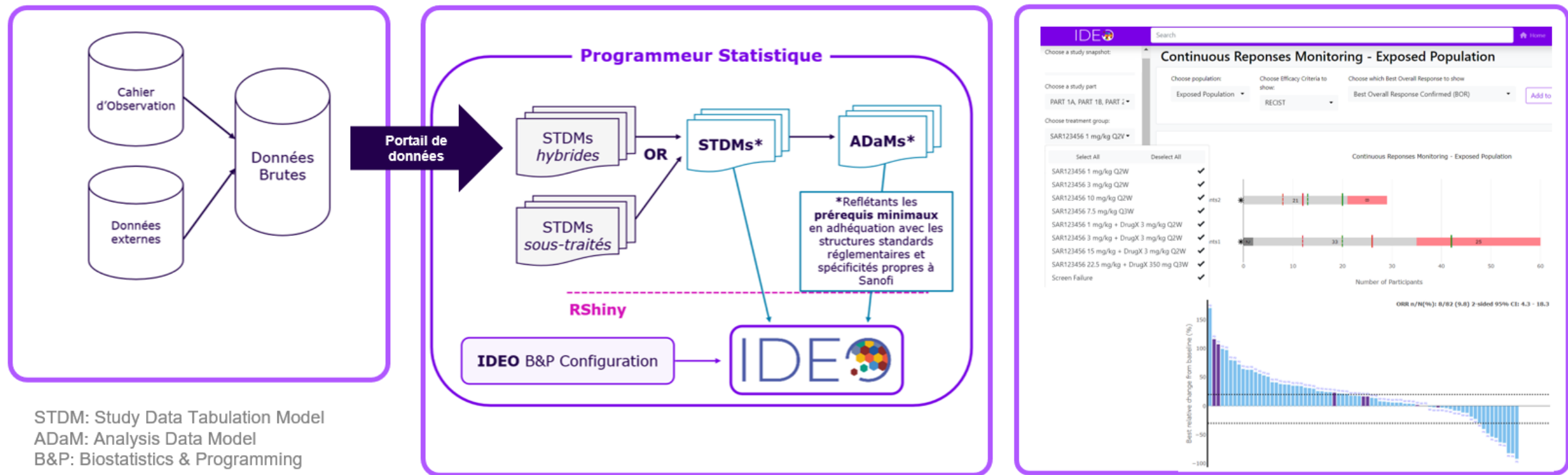


IDEO cheminement des informations menant à la prise de décision

Intégration et supervision continue des données brutes collectées auprès des sites investigateurs

Préparation des données brutes en données formatées répondant aux besoins structurels réglementaires et aux analyses statistiques

Mise à disposition de visualisations automatisées, intuitives et soutenant des prises de décisions rapides et éclairées



Choisir une étude



The screenshot shows the IDEO app interface. At the top is a purple header with the IDEO logo, a search bar, and navigation links: Home, Study info, Feedback, Support, and Sign out. Below the header, a dark blue arrow points to a dropdown menu titled 'Choose a study snapshot:'. The dropdown is open, showing a search bar and a list of study snapshots: 'APPS/IDEO - Test data for early onco (RECIST + biomarkers)', 'APPS/IDEO - Test data for early onco (RECIST + iRECIST)', and 'SAR12345/TED123456 - Ongoing data'. To the right of the dropdown, the text 'Welcome on IDEO app' is visible. A purple callout box with white text explains the dropdown menu's function.

Choose a study snapshot:

Search

Home Study info Feedback Support Sign out

Welcome on IDEO app

Le menu déroulant permet à l'utilisateur de voir uniquement les études disponibles et auquel il/elle est autorisé.e à accéder

APPS/IDEO - Test data for early onco (RECIST + biomarkers)
APPS/IDEO - Test data for early onco (RECIST + iRECIST)
SAR12345/TED123456 - Ongoing data

±150

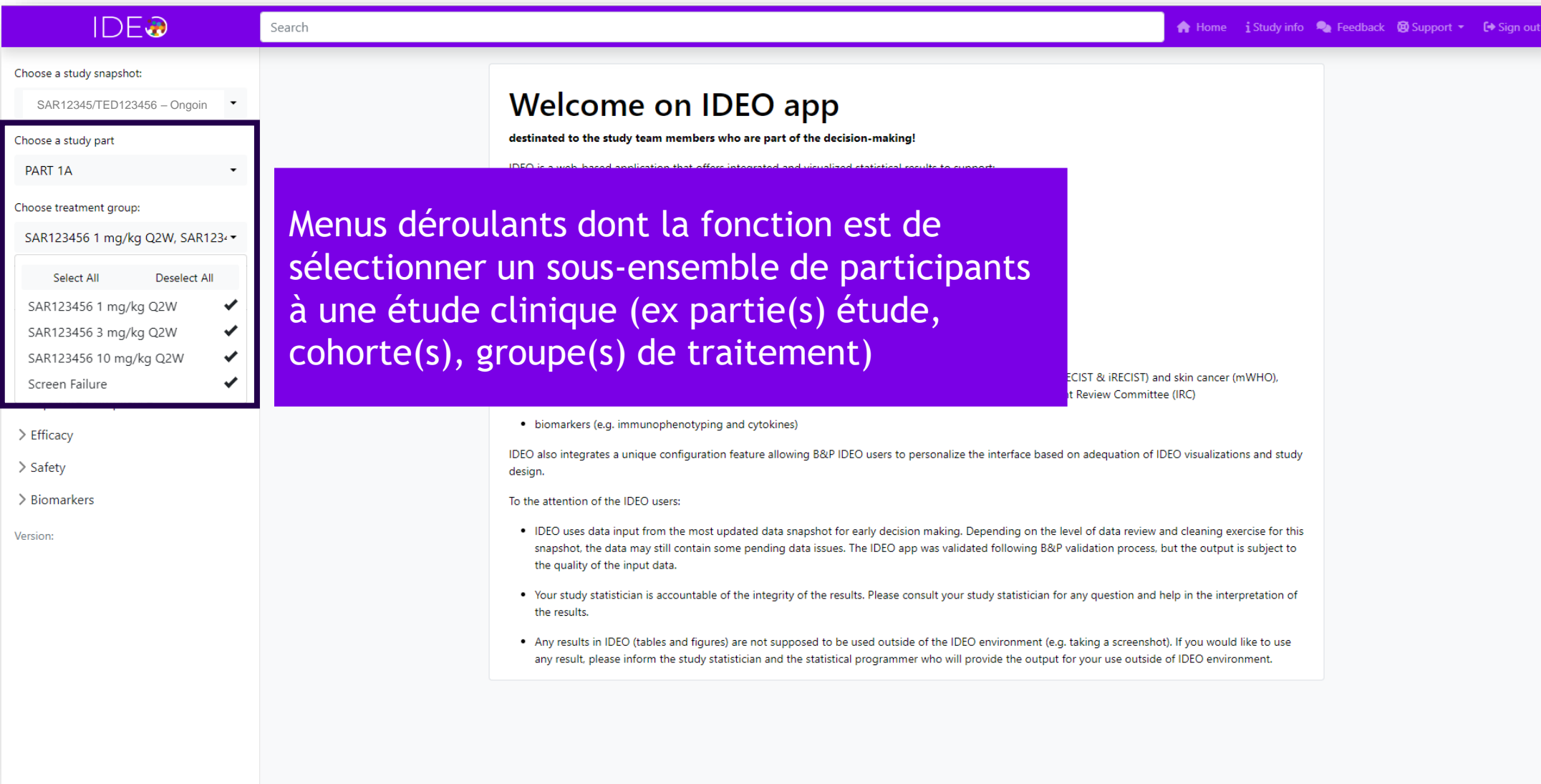
utilisateurs déclarés

*accès aux études contrôlé,
et basé sur le rôle*

20 études

**de phase précoce
en oncologie**

Filtrer les groupes de participants



The screenshot displays the IDEO app interface. On the left, a sidebar contains three dropdown menus for filtering: 'Choose a study snapshot:', 'Choose a study part:', and 'Choose treatment group:'. A red arrow points to the 'Choose treatment group:' dropdown, which is currently open, showing a list of treatment groups with checkboxes. The main content area on the right features a 'Welcome on IDEO app' message, a search bar, and navigation links (Home, Study info, Feedback, Support, Sign out). A large red text box is overlaid on the right side of the interface.

Choose a study snapshot:

SAR12345/TED123456 – Ongoing

Choose a study part

PART 1A

Choose treatment group:

SAR123456 1 mg/kg Q2W, SAR123456 3 mg/kg Q2W, SAR123456 10 mg/kg Q2W, Screen Failure

Select All Deselect All

SAR123456 1 mg/kg Q2W ✓

SAR123456 3 mg/kg Q2W ✓

SAR123456 10 mg/kg Q2W ✓

Screen Failure ✓

> Efficacy

> Safety

> Biomarkers

Version:

Welcome on IDEO app

destined to the study team members who are part of the decision-making!

IDEO is a web-based application that offers integrated and visualized statistical results to support...

RECIST & iRECIST) and skin cancer (mWHO),
t Review Committee (IRC)

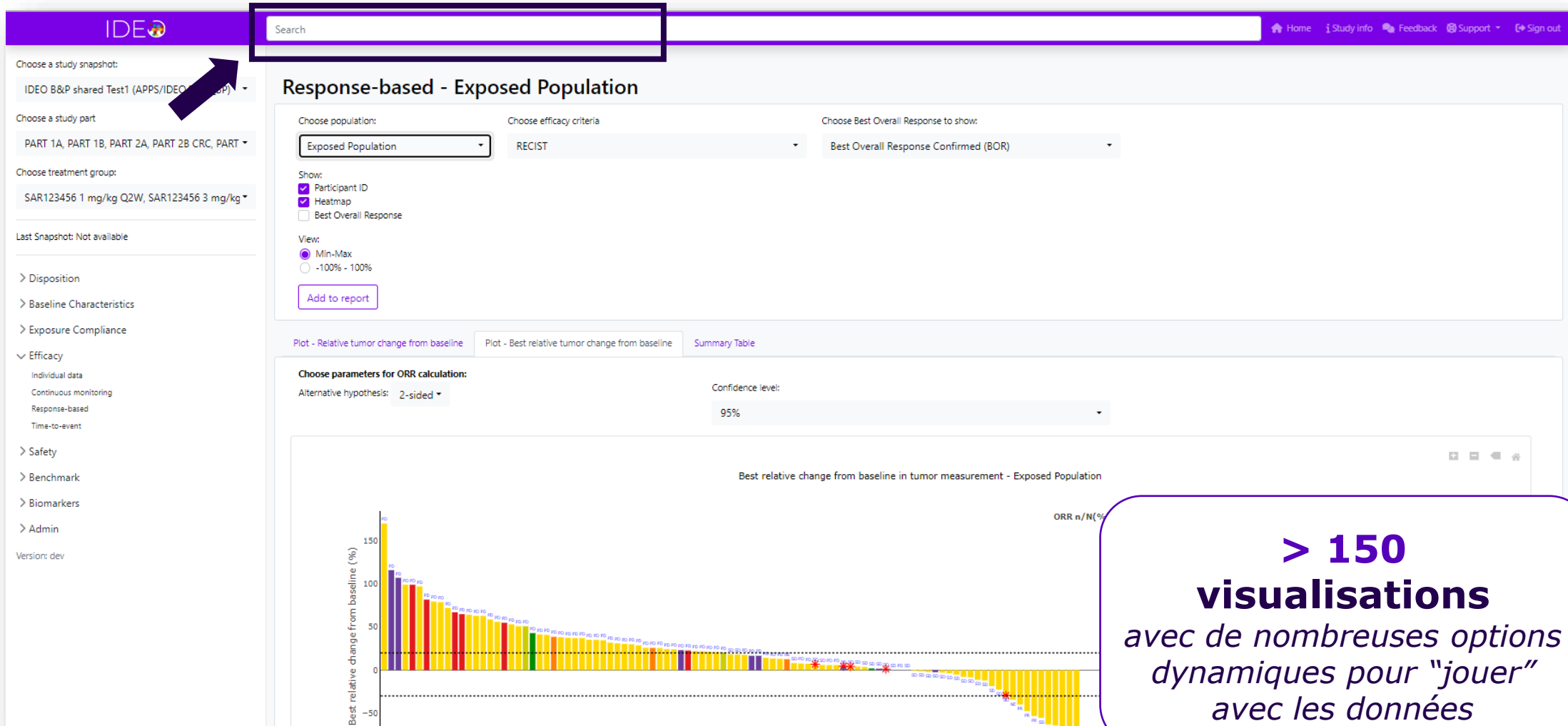
• biomarkers (e.g. immunophenotyping and cytokines)

IDEO also integrates a unique configuration feature allowing B&P IDEO users to personalize the interface based on adequation of IDEO visualizations and study design.

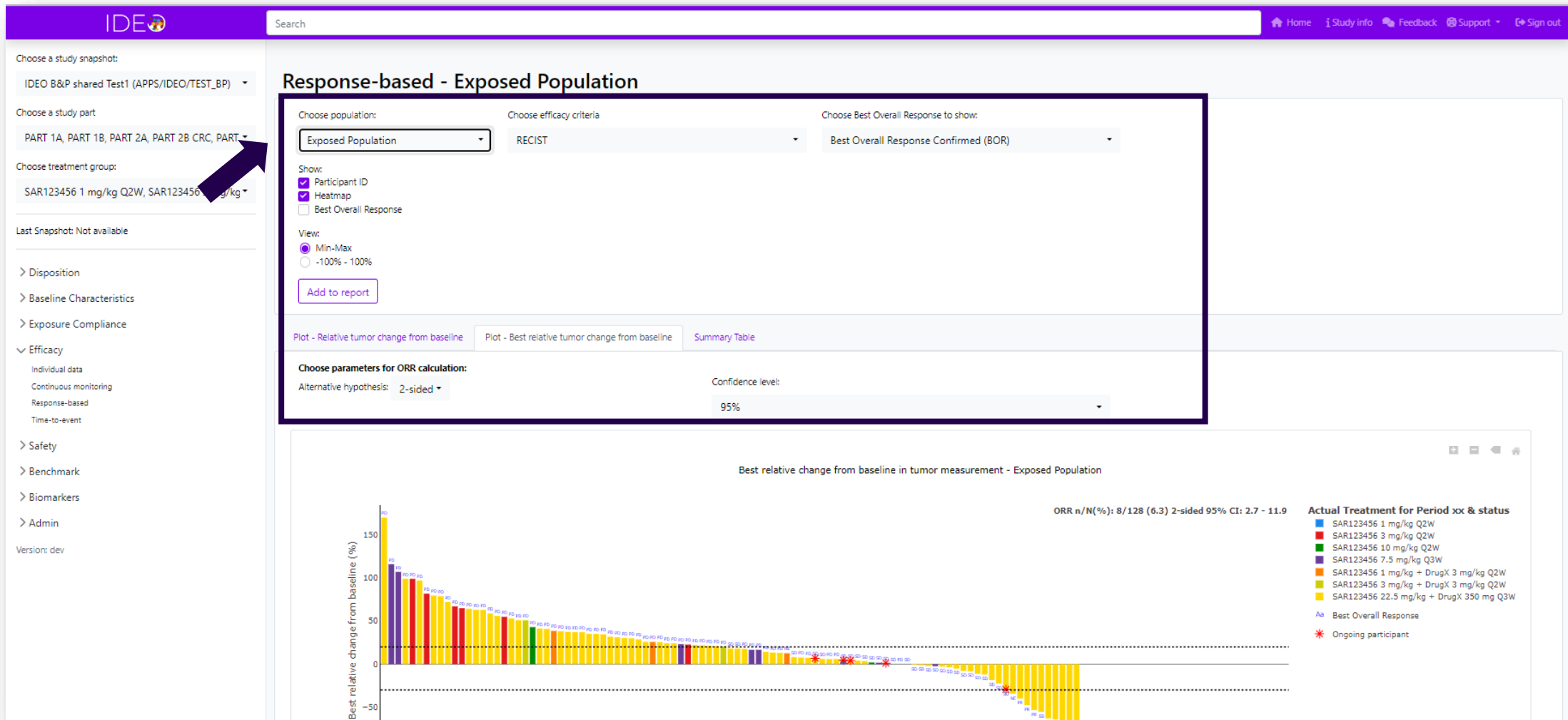
To the attention of the IDEO users:

- IDEO uses data input from the most updated data snapshot for early decision making. Depending on the level of data review and cleaning exercise for this snapshot, the data may still contain some pending data issues. The IDEO app was validated following B&P validation process, but the output is subject to the quality of the input data.
- Your study statistician is accountable of the integrity of the results. Please consult your study statistician for any question and help in the interpretation of the results.
- Any results in IDEO (tables and figures) are not supposed to be used outside of the IDEO environment (e.g. taking a screenshot). If you would like to use any result, please inform the study statistician and the statistical programmer who will provide the output for your use outside of IDEO environment.

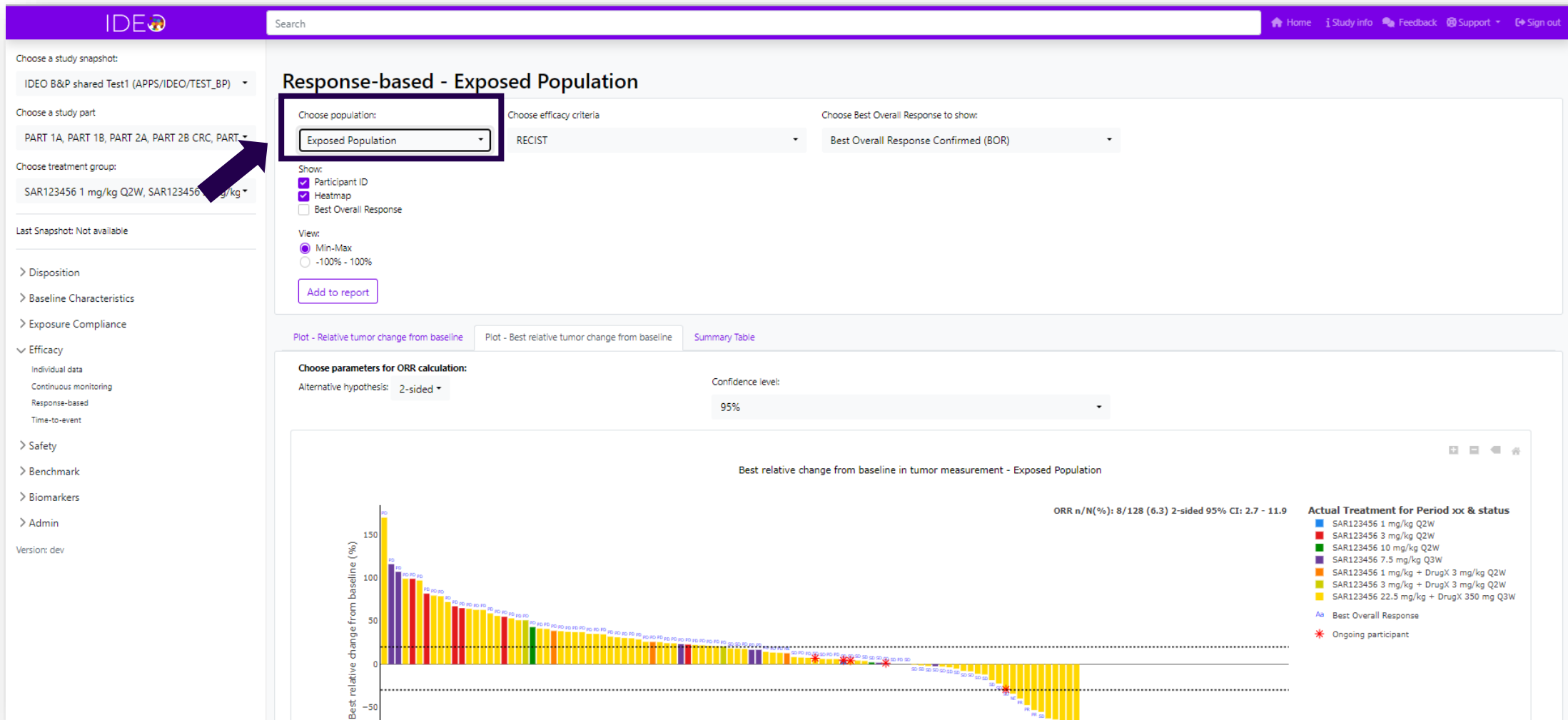
Choisir la visualisation adaptée à la question



Ajustement des options à l'aide des panels de contrôle des visualisation et des spécifications d'analyses statistiques



Ajustement des options à l'aide des panels de contrôle des visualisation et des spécifications d'analyses statistiques



Configuration depuis un module dédié – retreint pour B&P

IDEO

Search

Choose a study snapshot:

IDEO B&P shared Test1 (APPS/IDEO/TEST_BP)

Choose a study part:

PART 1A, PART 1B, PART 2A, PART 2B CRC, PART :

Choose treatment group:

SAR123456 1 mg/kg Q2W, SAR123456 3 mg/kg

Last Snapshot: Not available

> Disposition

> Baseline Characteristics

> Exposure Compliance

✓ Efficacy

Individual data

Continuous monitoring

Response-based

Time-to-event

> Safety

> Benchmark

> Biomarkers

✓ Admin

Report

Profile

Admin

Config

Save

Analysis population

Select population flags for each section:

Baseline Characteristics

EXPOSEFL, SCREENFL, EXPOSEFL, SCREEN

Benchmark

EXPOSEFL, EXPOSEFL

Biomarkers

EXPOSEFL, EXPOSEFL

Disposition

EXPOSEFL, EXPOSEFL

Efficacy

RESPEFL, EXPOSEFL

Exposure Compliance

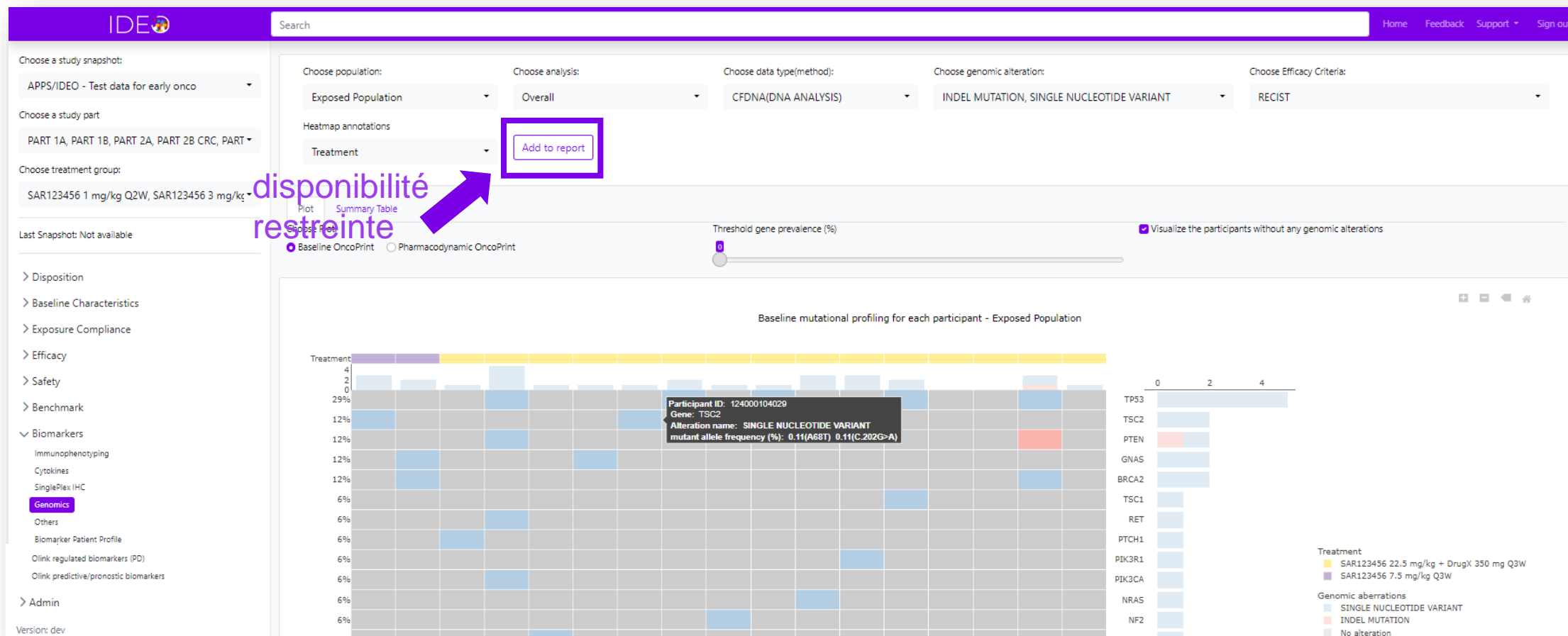
EXPOSEFL, SAFFL, SCREENFL, EXPOSEFL, :

Safety

EXPOSEFL, EXPOSEFL

disponibilité
restreinte

Téléchargement des visualisation(s) d'intérêt pour un partage stabilisé au delà des vues interactives – **restreint pour B&P**





Des visualisations interactives dont la création est validée et la mise à disposition est sécurisée pour une prise de décision plus rapide, fiable, et reposant sur un flux de données consolidé depuis la source promouvant

- automatisation
- standards flexibles
- interface conviviale
- compréhension mutuelle et coopération

	SAR1213456 3 mg/kg + Drug X3 mg/kg Q2W (N=3)	SAR1213456 22.5 mg/kg + Drug X 350 mg Q3W (N=101)	All (N=104)
Participants with ADA negative or missing at baseline n/N1 ^a	3/3 (100)	100/101 (99.0)	103/104 (99.0)
Participants with treatment-induced ADA n/N1 ^a	0/3	1/100 (1.0)	1/103 (1.0)
Number		1	1
Median peak titer (1/dil)		12.0	12.0
Q1 : Q3 peak titer (1/dil)		12.0 ; 12.0	12.0 ; 12.0
Min ; Max peak titer (1/dil)		12 ; 12	12 ; 12
Persistent ADA response n/N1 ^a	0	0	0
Transient ADA response n/N1 ^a	0	0	0
Indeterminate ADA response n/N1 ^a	0	1 (100)	1 (100)
Participants with ADA positive at baseline n/N1 ^a	0/0	1/10 (10.0)	1/10 (10.0)
Participants with treatment-boosted ADA n/N1 ^a	0/0	1/1 (100)	1/1 (100)
Number		1	1
Median peak titer (1/dil)		10.0	10.0
Q1 : Q3 peak titer (1/dil)		10.0 ; 10.0	10.0 ; 10.0
Min ; Max peak titer (1/dil)		10 ; 10	10 ; 10
Persistent ADA response n/N1 ^a	0	0	0
Transient ADA response n/N1 ^a	0	1 (100)	1 (100)
I ^a = 100% = NCLCTCAE term	0	0	0

Choose a NCI-CTCAE term

BM1LOQ = NA

Activated partial thromboplastin time prolonged

ADA I	0/104
ADA	0/104

— 100 —

At least one Grade ≥ 3

Alkaline phosphatase increased

Anemia

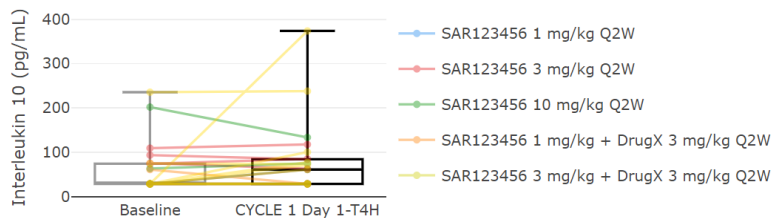
Aspartate aminotransferase increased

Blood bilirubin increased

All Others

Activated partial thromboplastin time prolonged

Alanine aminotransferase increased



Tabs	Heatmap	Column Headers	Treatment arms	Analysis population	Blinding
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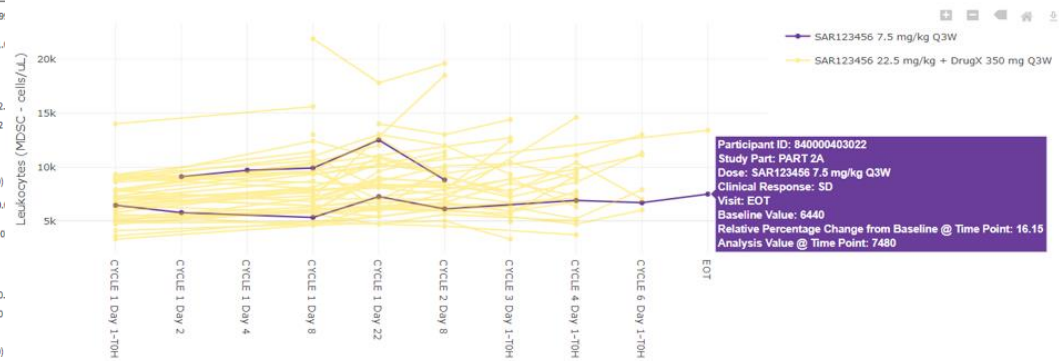
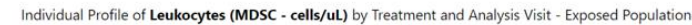
How blinding works:

- By default, only late oncology analysis are blinded.
- Blinding data will recode treatment identifying variables for all datasets.

This analysis is **not blinded** in IDEO.

➡ ☐ Apply blindings

Save



Participant ID: 840000403022
Study Part: PART 2A
Dose: SAR123456 7.5 mg/kg Q3W
Clinical Response: SD
Visit: EOT
Baseline Value: 6440
Relative Percentage Change from Baseline @ Time Point: 16.15
Analysis Value @ Time Point: 7480

Change from Baseline Boxplot by Actual Treatment for Period xx and Visit Name

