From Customer-centric User Research to Data Visualization App:

A Journey of Developing Modules to Support Exploratory Biomarker Analysis

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Boehringer Ingelheim

Disclaimer

The views expressed in this talk are those of the speakers and not necessarily those of Boehringer Ingelheim

Source: N Engl J Med 2021; 385:2431-2440, DOI: 10.1056/NEJMoa2111563

Background: Generalized Pustular Psoriasis (GPP)

- Rare, potentially life-threatening skin disease
- Characterized by episodes of widespread eruption of sterile visible pustules
- Can occurr with or without systemic inflammation
- Flares are characteristic of the clinical course

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Background: Spesolimab

- In GPP the IL-36 pathway plays a key role
- Inhibition of IL-36 signaling may provide effective targeted treatment
- Spesolimab is a IL-36 receptor inhibitor to treat GPP

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Effisayil™ 1 - Spesolimab in Generalized Pustular psoriasis

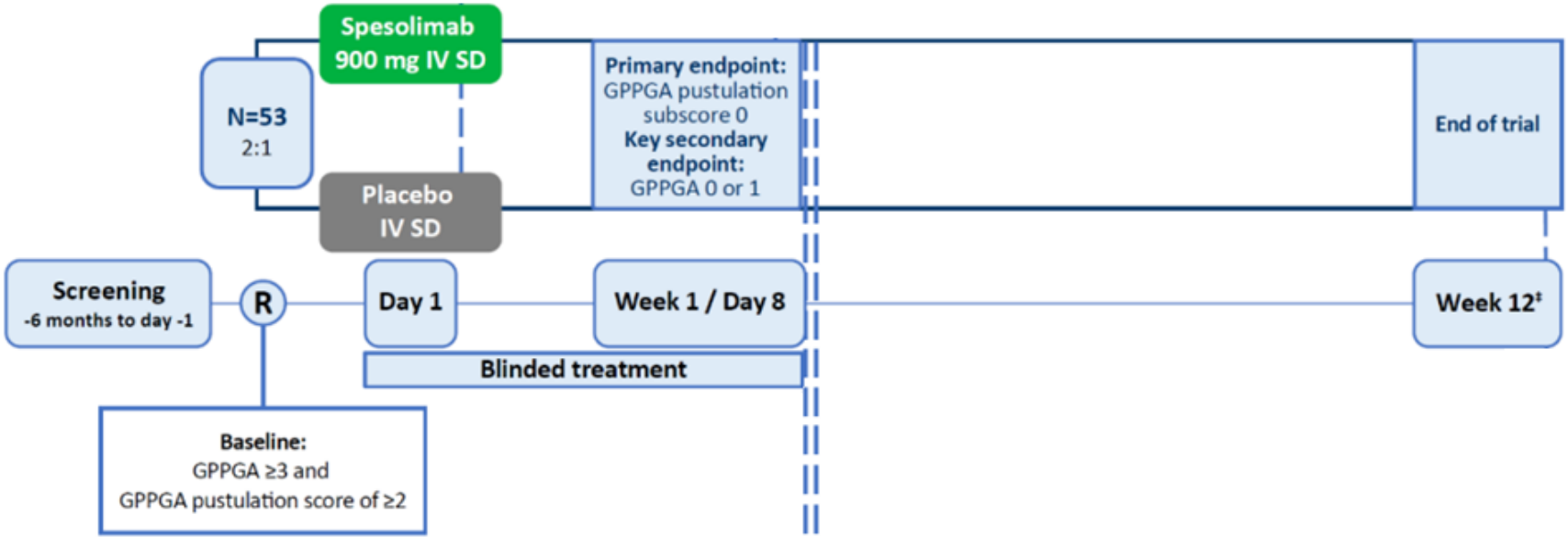

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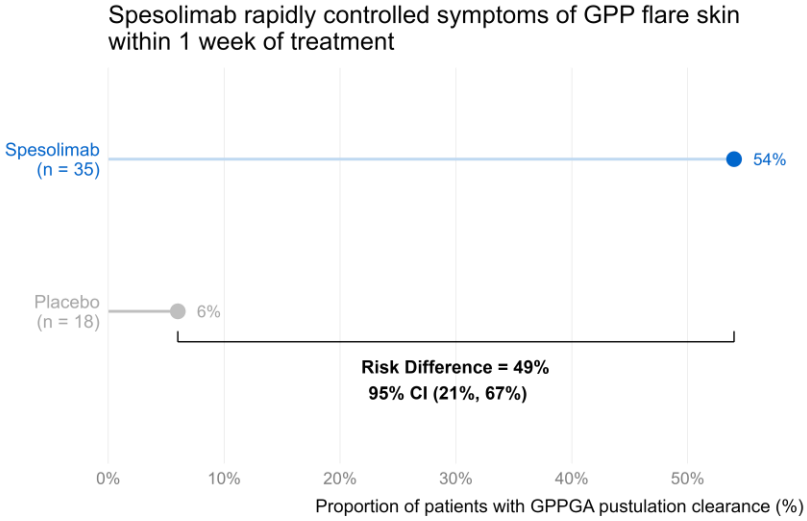
Figure S1 in Supplementary Appendix, slightly modified for the purpose of this presentation

Evidence of effectiveness + Strong mechanistic support

- Binary efficacy endpoint



- Continuous efficacy endpoint

Role of Biomarkers

- Provide strong mechanistic support
- Provide further insights into GPP disease and mode of action of spesolimab
- Biomarker focused presentations and publications

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Protein Biomarker Analysis and Visualization

Objectives

- Multiple protein biomarkers (from various pathways) should be analyzed and visualized
- Link to main clinical efficacy endpoint(s) should be presented
- Integration of relevant baseline variables and/or other binary efficacy endpoints of interest

Protein Biomarker Analysis and Visualization

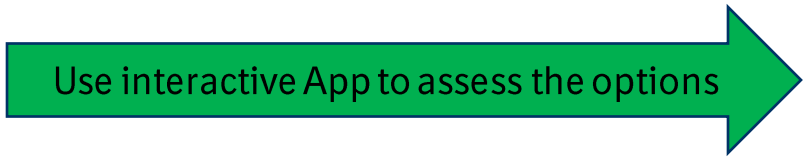
Objectives

- Multiple protein biomarkers (from various pathways) should be analyzed and visualized → heatmap
- Link to main clinical efficacy endpoint(s) should be presented → sorting of patients via waterfall plot
- Integration of relevant baseline variables and/or other binary efficacy endpoints of interest → extra panels

Protein Biomarker Analysis and Visualization

Variety of options for the implementation

- Which biomarkers to be integrated and how to order?
- What clinical, baseline and/or subgroup features should be integrated?
- Which time point(s) are most important?
- What scaling and coloring is most suitable?
- Should certain patients be excluded (e.g. due to unavailability of data)?
- What kind of labels are required?



WHY? - Motivation

From:

Static Data Review
Focus: **Tables**

2.3.2 Clinical laboratory evaluation

2.3.2.1 LABPCS - Possibly clinically significant abnormalities

Parameter Treatment	N	Number analysed[1]	Low		High	
			N	%	N	%
Lab parameter 1						
Treat 1	xxx	xxx	xxx	xx.x	xxx	xx.x
<Treat k>	xxx	xxx	xxx	xx.x	xxx	xx.x
<Lab parameter n>						
Treat 1	xxx	xxx	xxx	xx.x	xxx	xx.x
<Treat k>	xxx	xxx	xxx	xx.x	xxx	xx.x

[1] Subjects with no possibly clinically significant abnormality at baseline
Empty columns or lines indicate that there are no corresponding rules defined.
Subjects may be counted twice per parameter and treatment when meeting low and high

- PDF/PPT-based review
- Non-linked outputs
- Specific data snapshots required

Existing gap for **interactive, real-time data visualization** to support
- trial oversight & decision making
- statistical novelties

To:

Interactive data review
Focus: **Graphics**

- Web-based
- Linked outputs
- Real-time and interactive

Effective & focused trial oversight
- Review, incl. deep-dive option
- Align & share insights during meetings

Faster clinical insights generation and more **agile decision making**

And beyond...

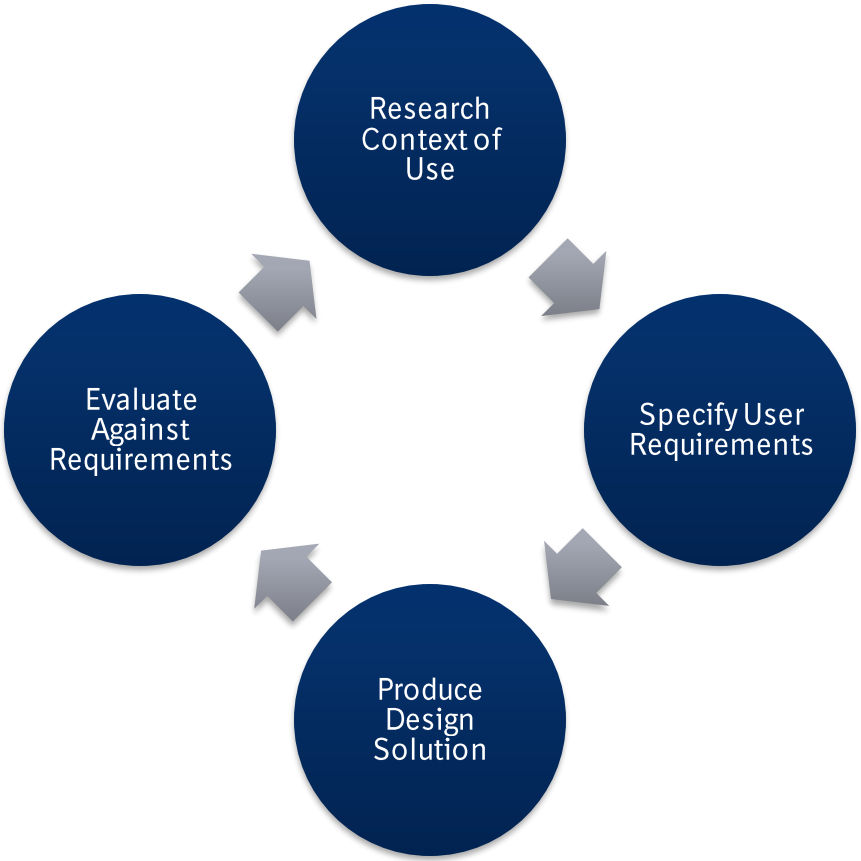
Storytelling with data

Unleash the power of data through visualization: Consider new ways of reviewing and presenting data

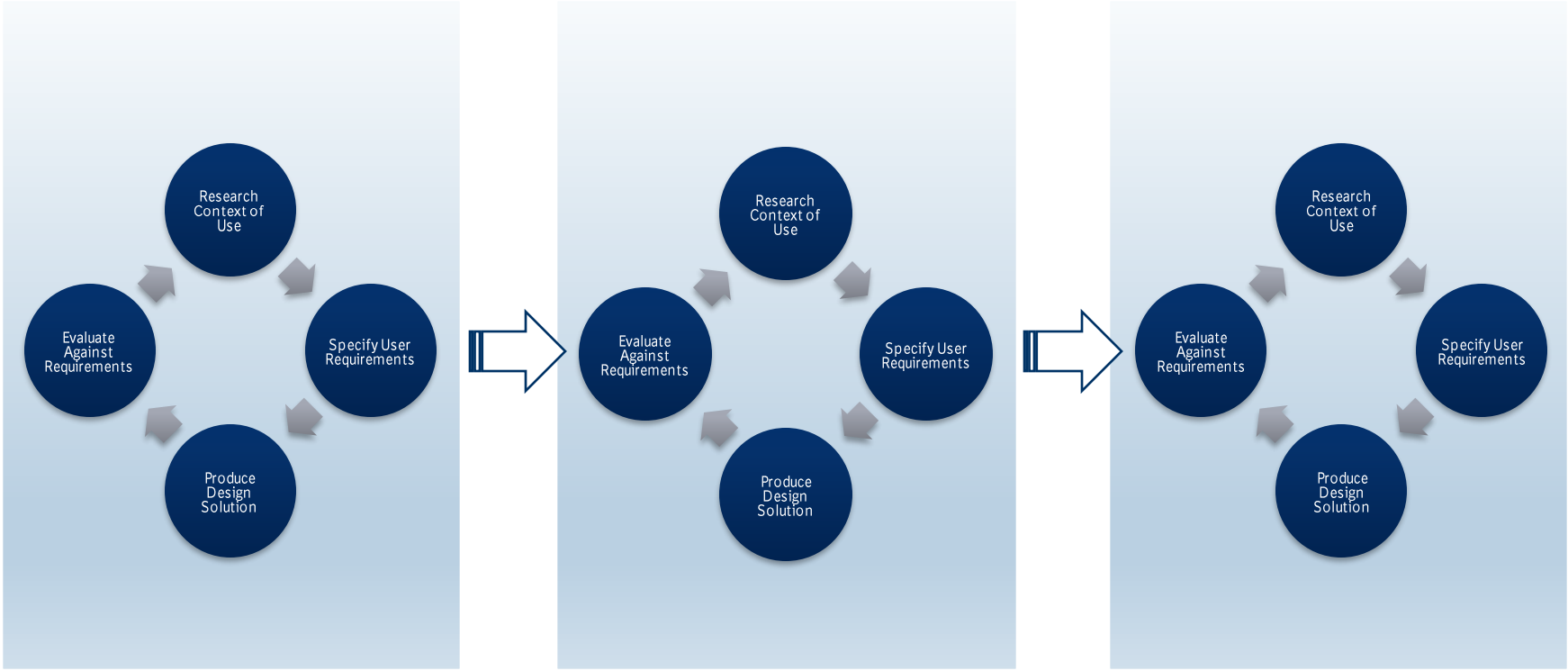
Use advanced graphics to support implementation of new statistical methods

Guide your team through the data

From Customer-centric User Research to Data Visualization App



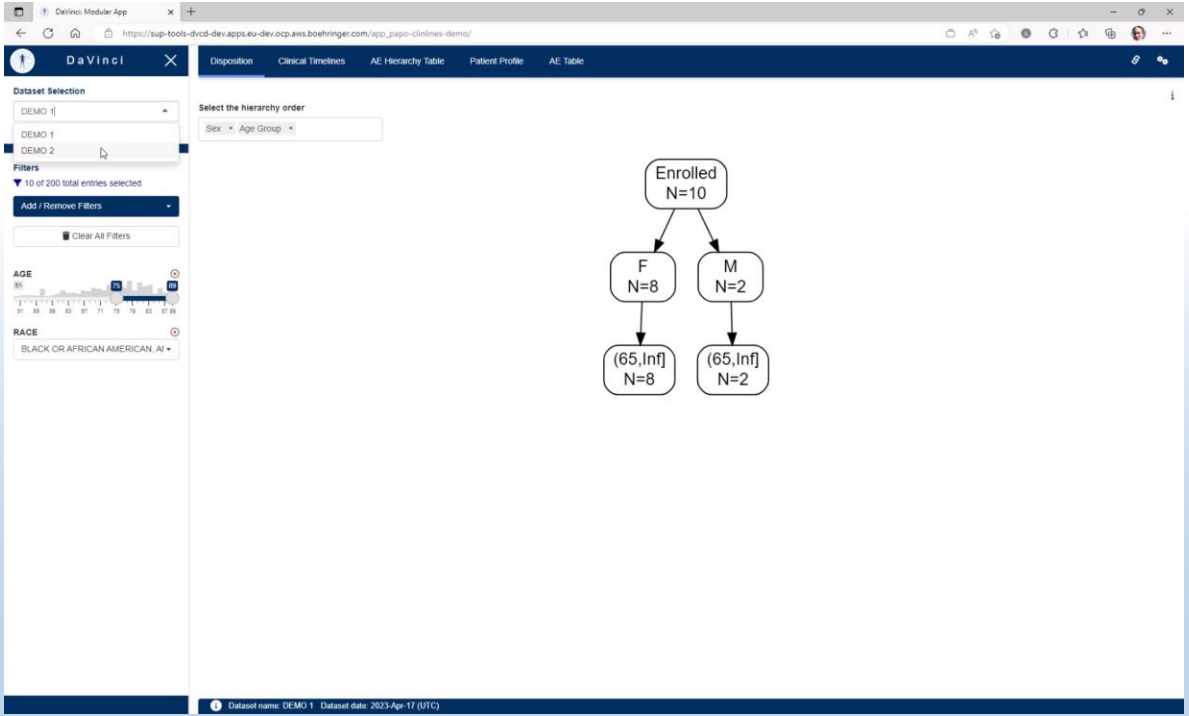
From Customer-centric User Research to Data Visualization App



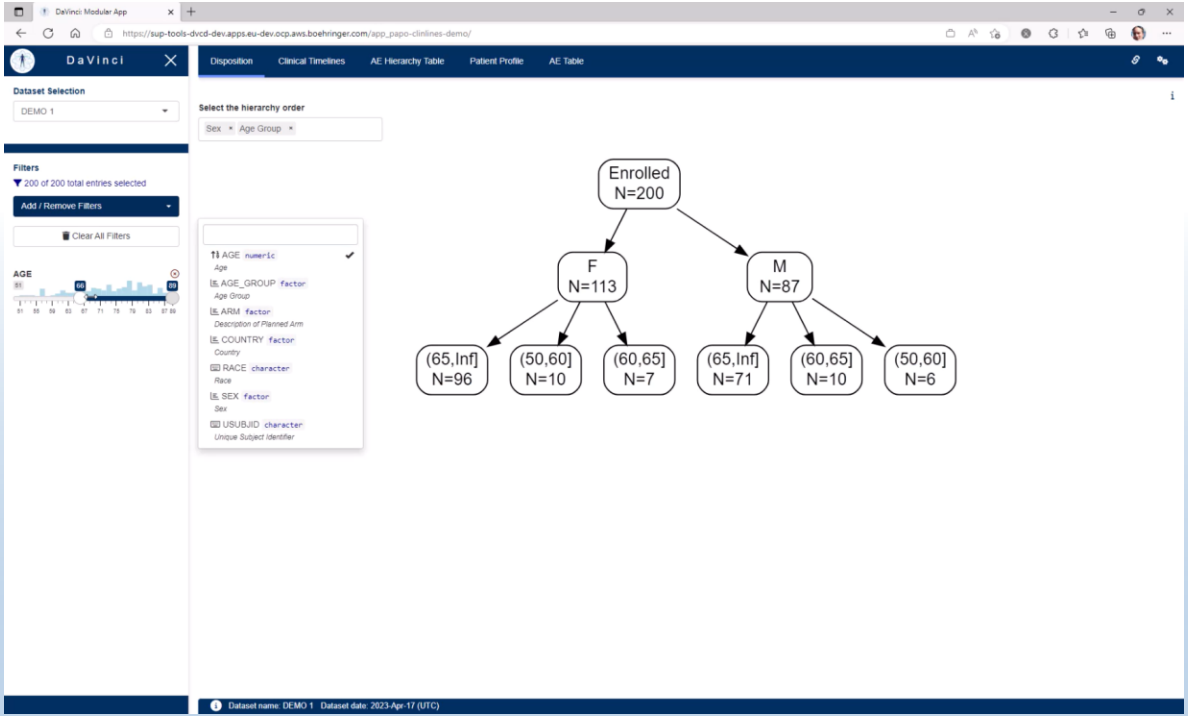
The Concept of the Modular Approach

- DaVinci Modules are functional building blocks composable into customized Apps
- This customization enables the building of Apps according to **trial** and **project-specific** needs
- Enables teams to use best-practice templates with a common look-and-feel
- The Hosting Platform allows to create, integrate and deploy Apps.

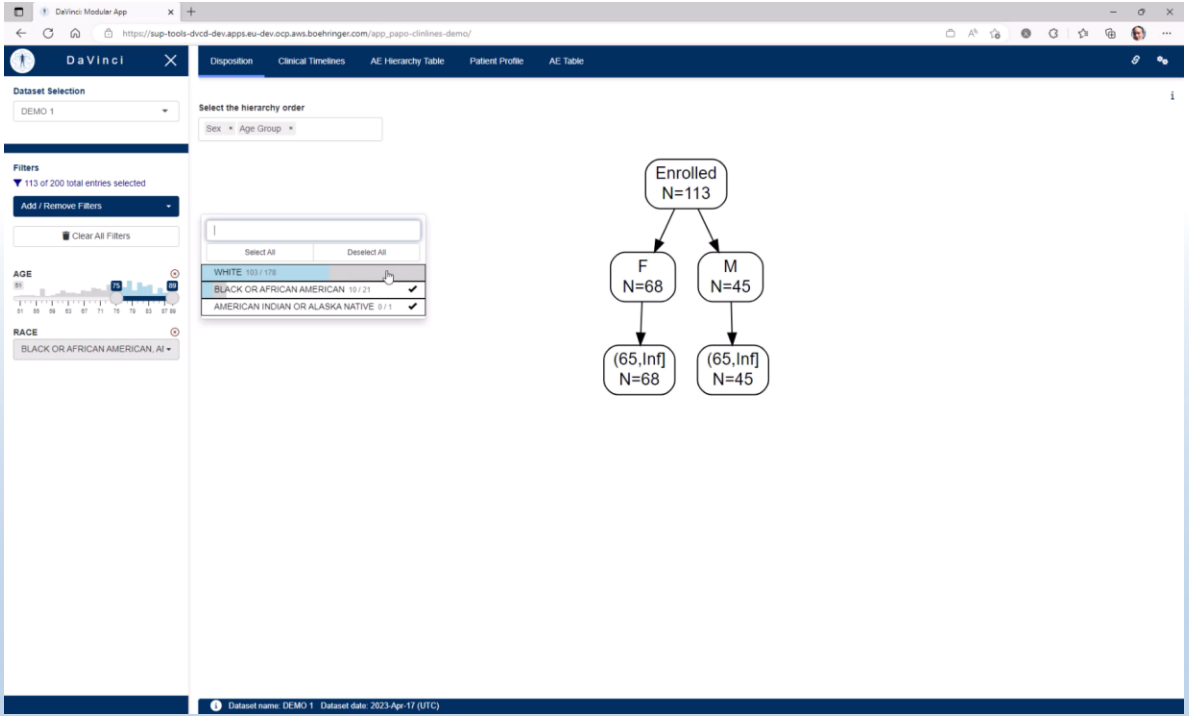
Modular Approach: Data Selection



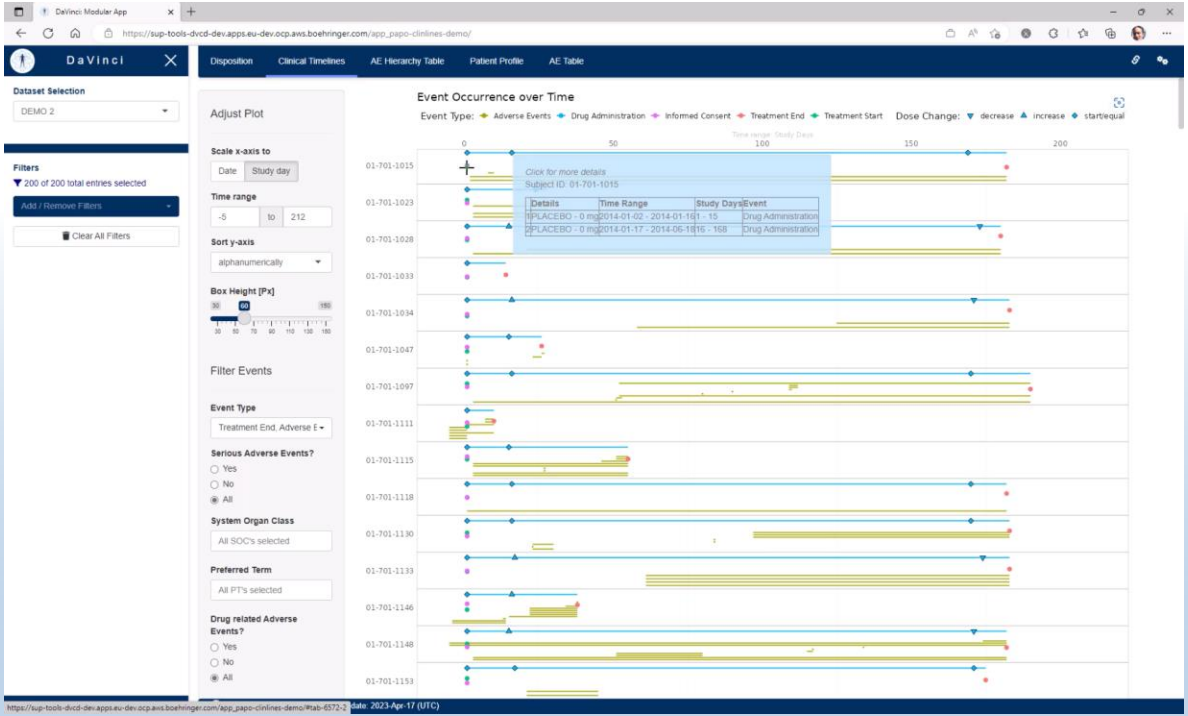
Modular Approach: Subject filtering by Contineous Variable



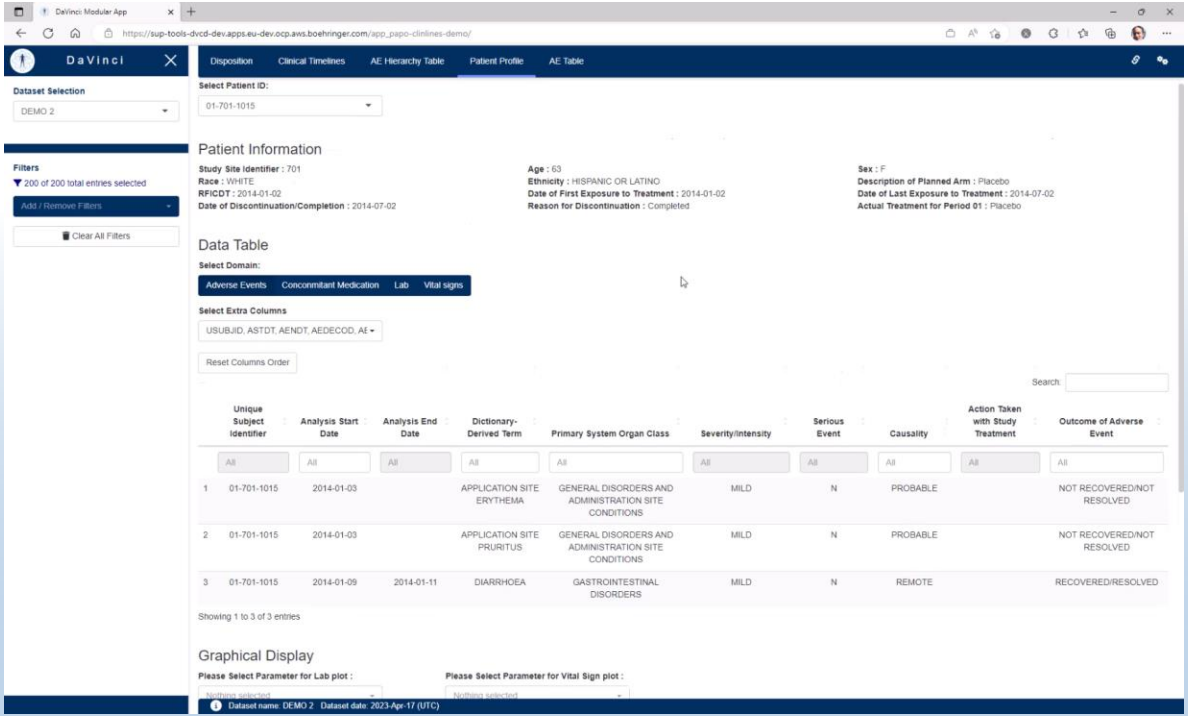
Modular Approach: Subject filtering by Categorical Variable



Modular Approach: The Clinical Timelines Module



Modular Approach: The Patient Profile Module



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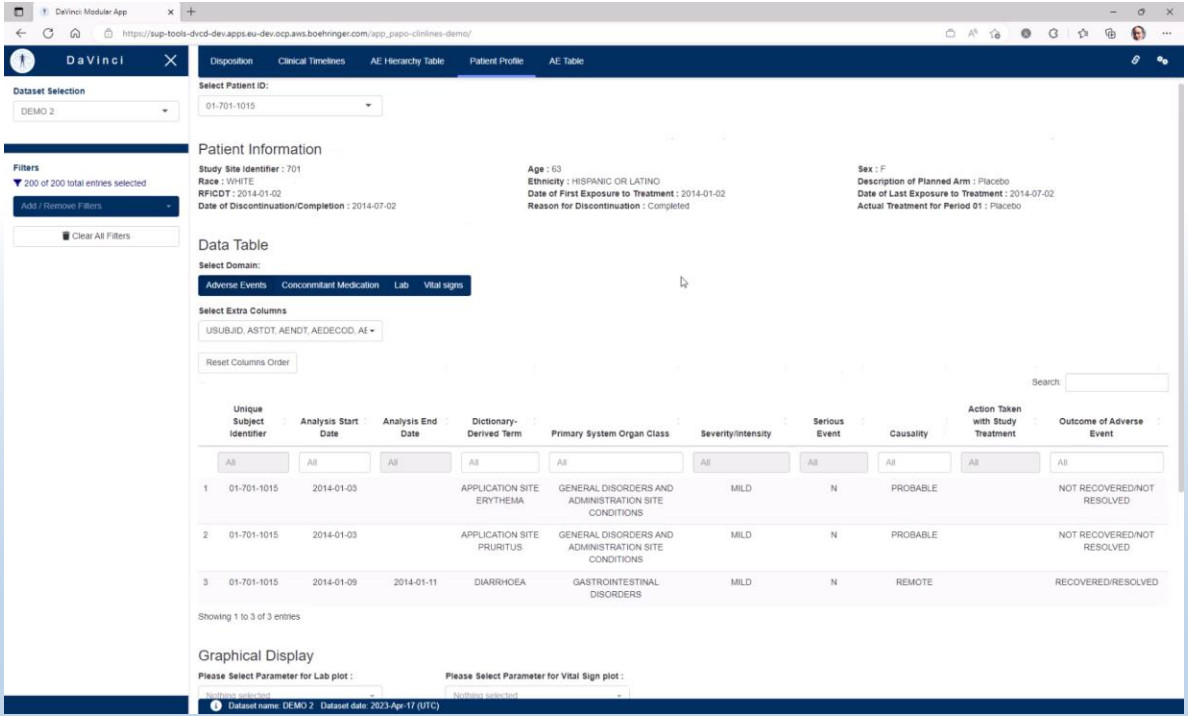
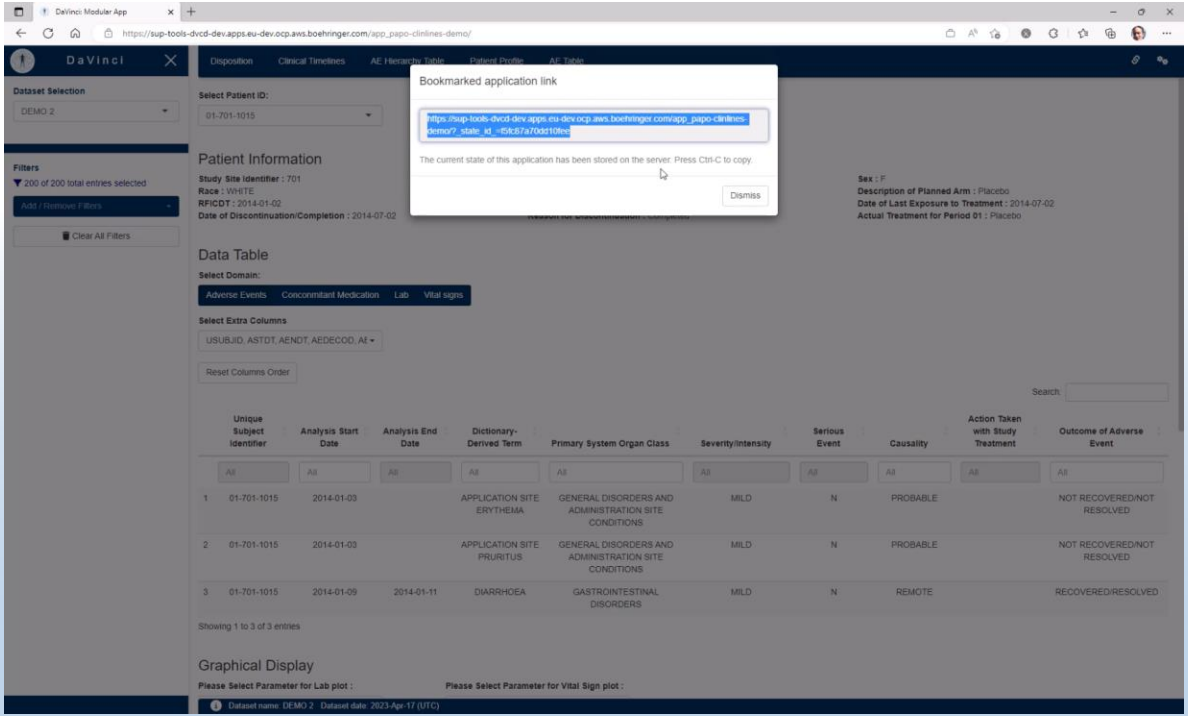
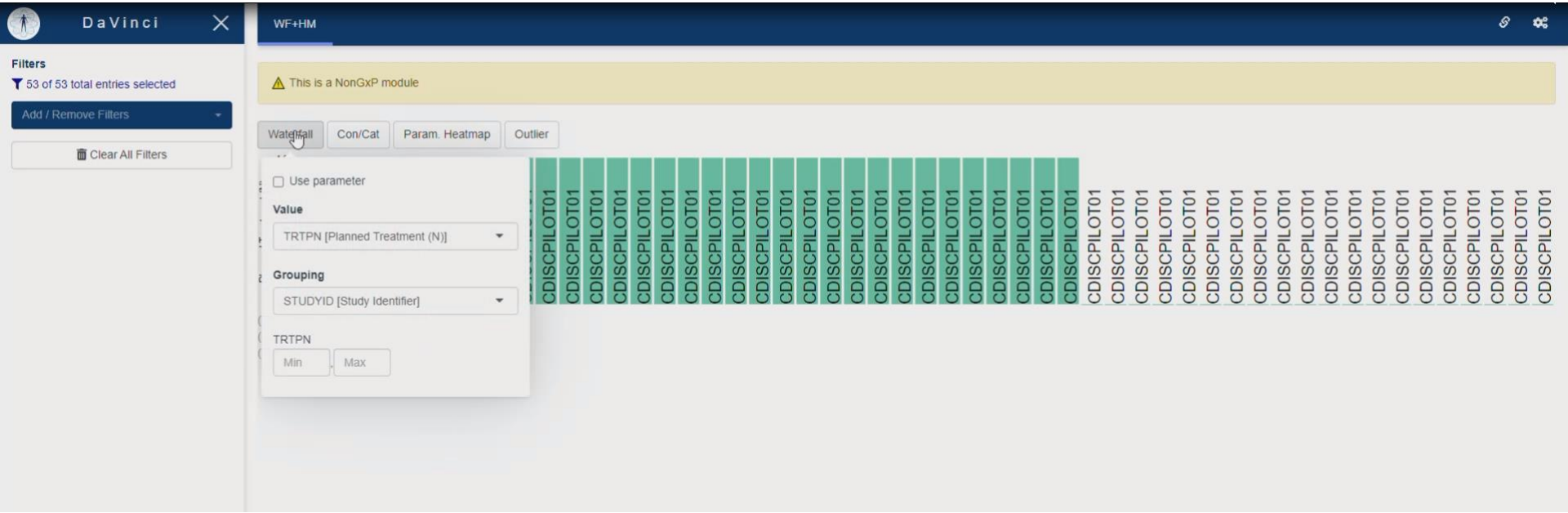


Modular Approach: Bookmark functionality



Backup (App demo)

Note: Artificial dummy data has been used for the demonstration



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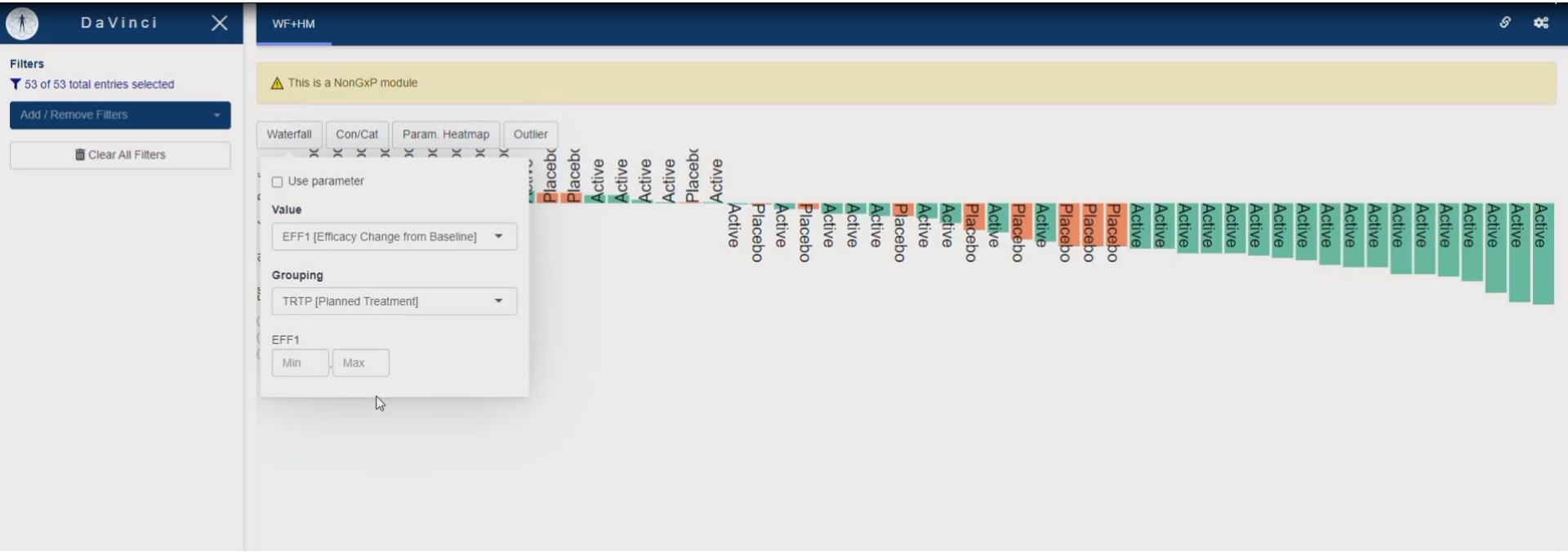

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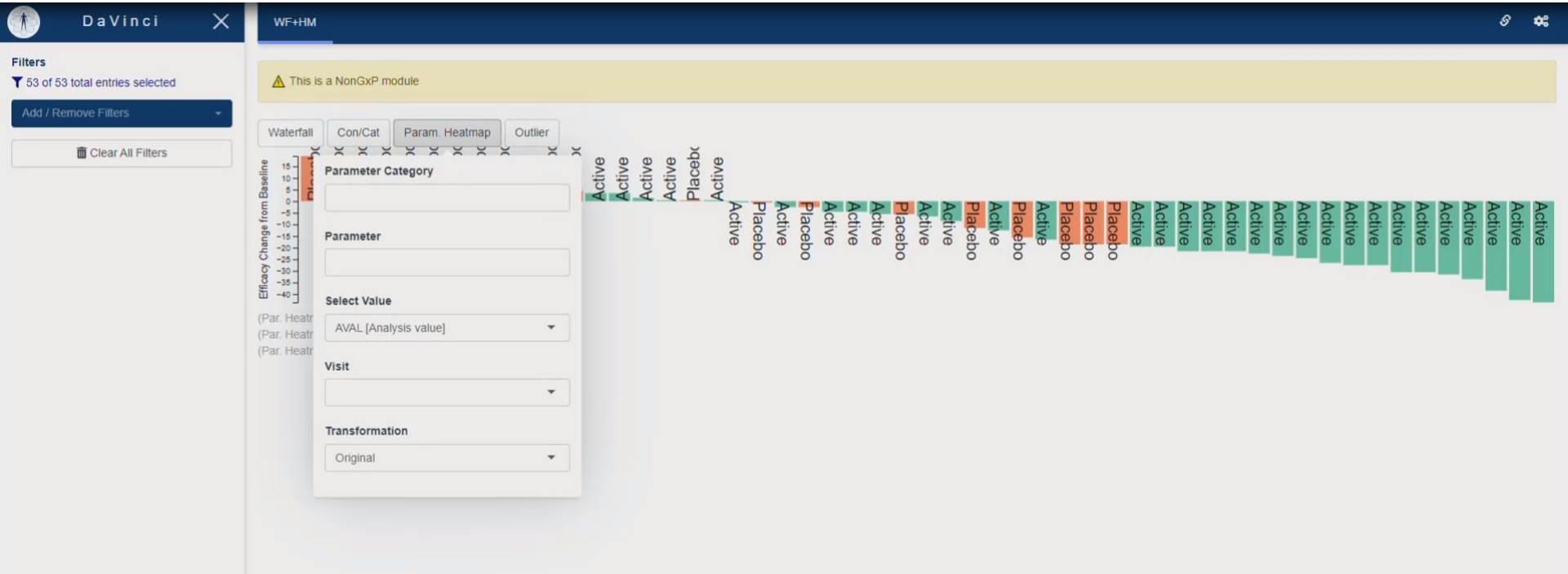

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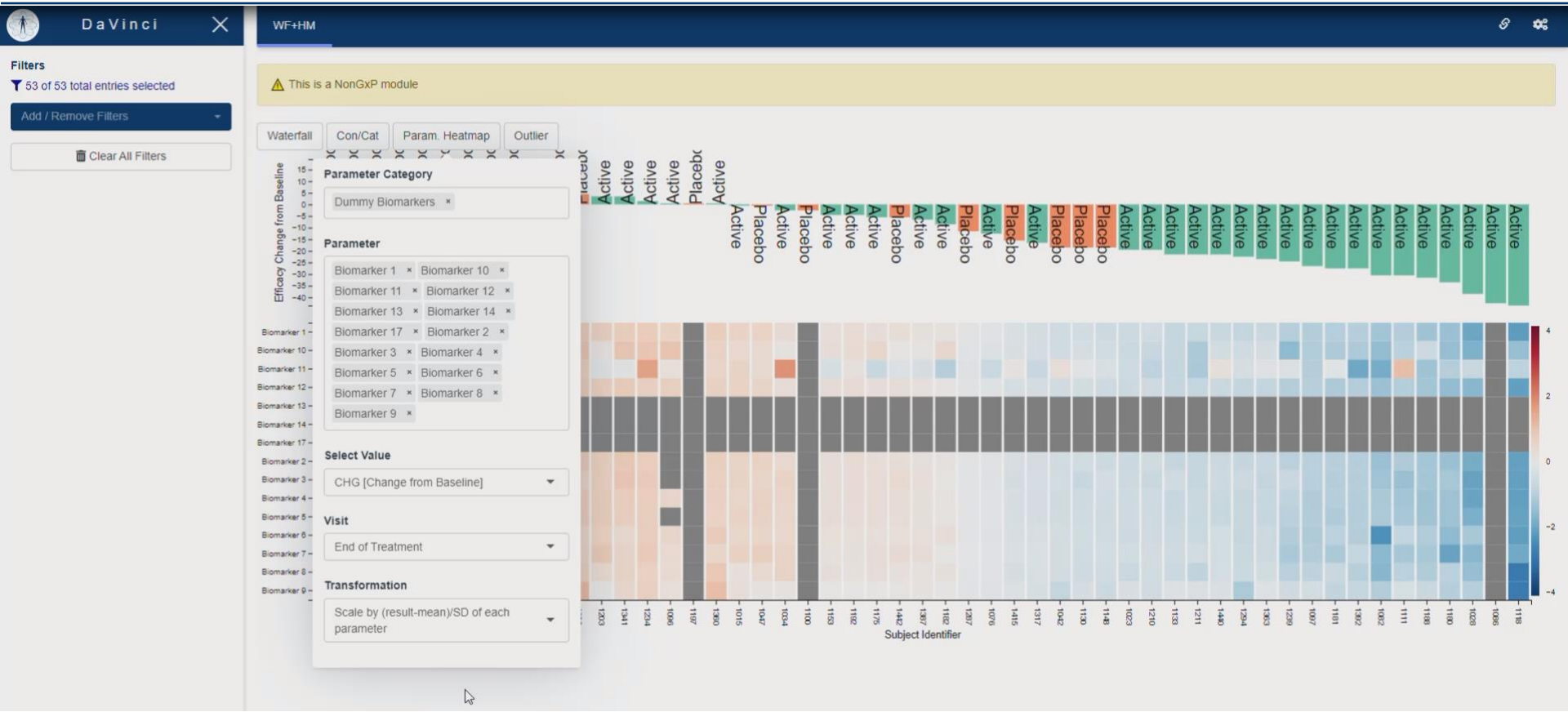

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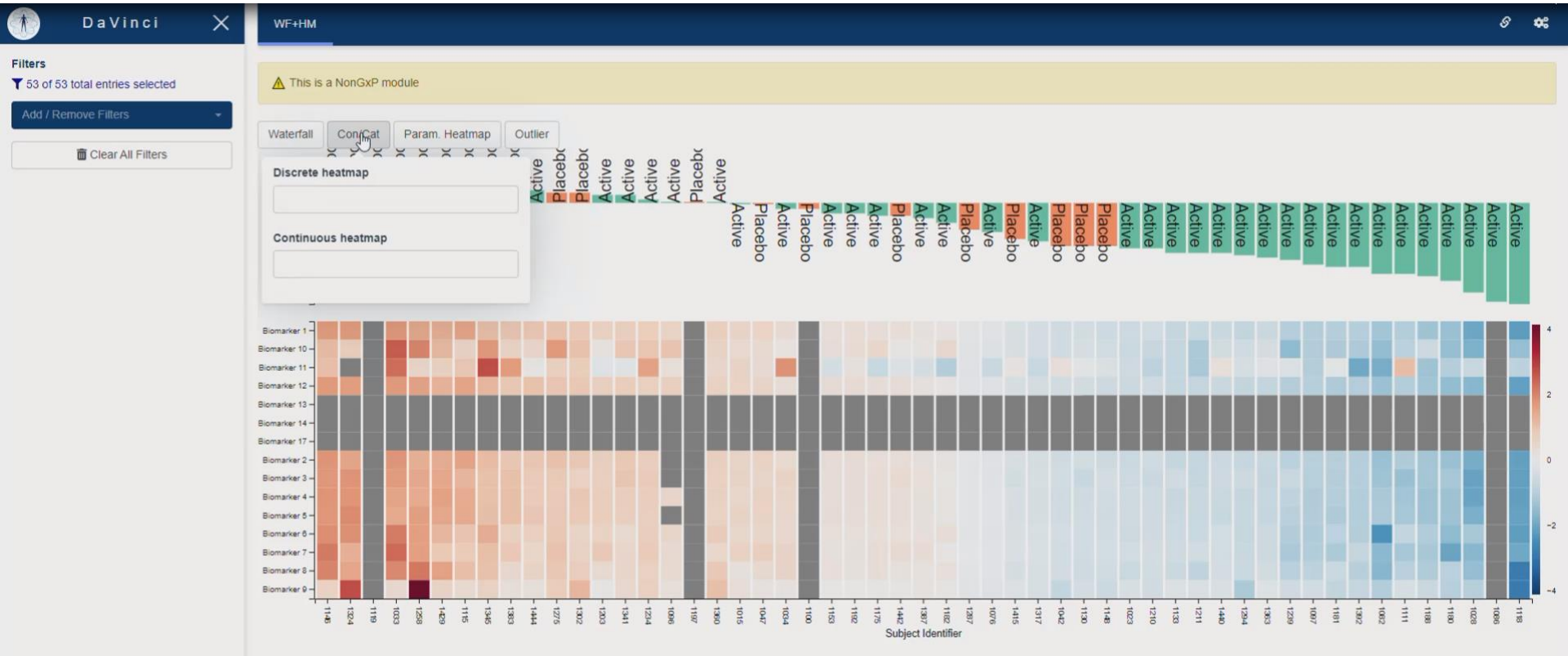

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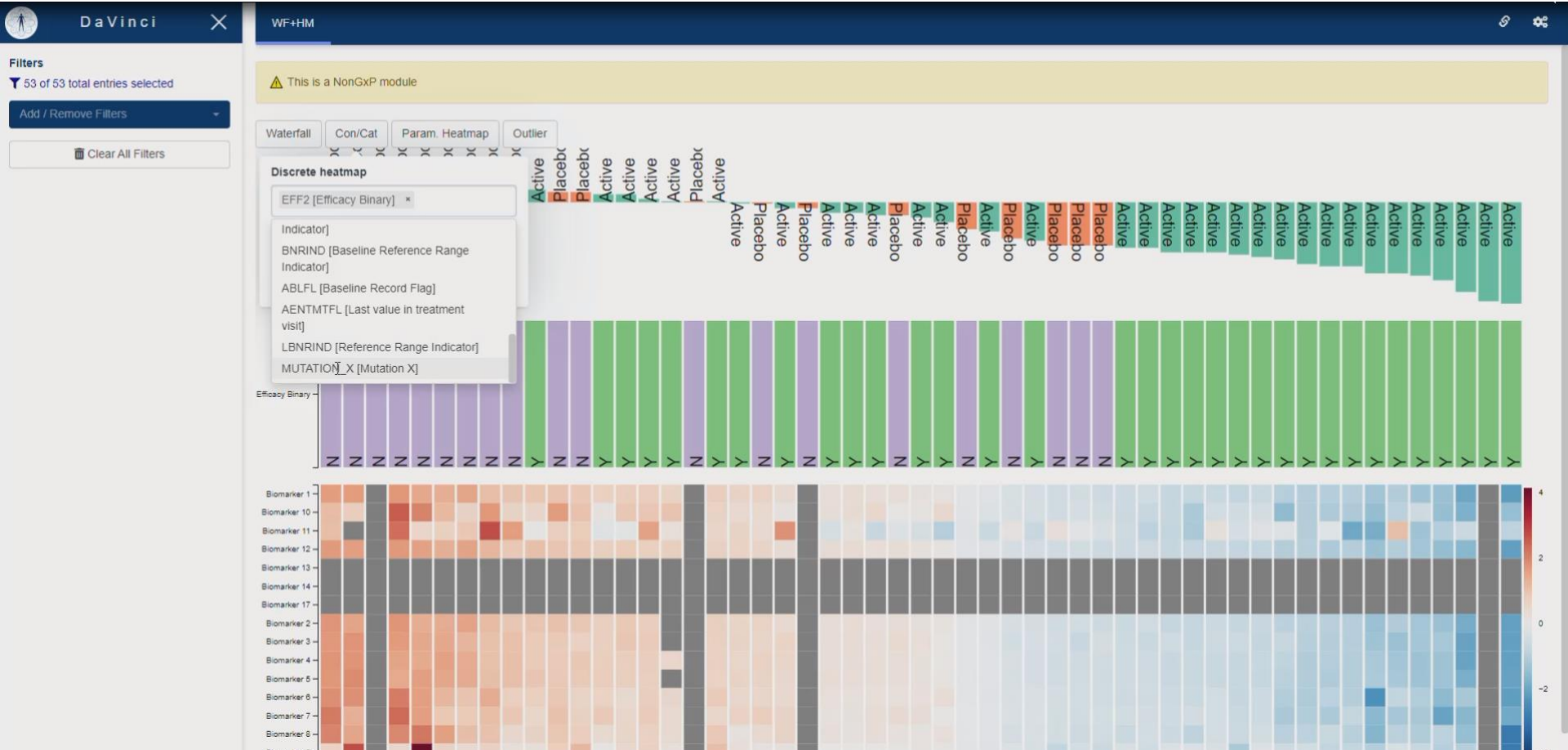

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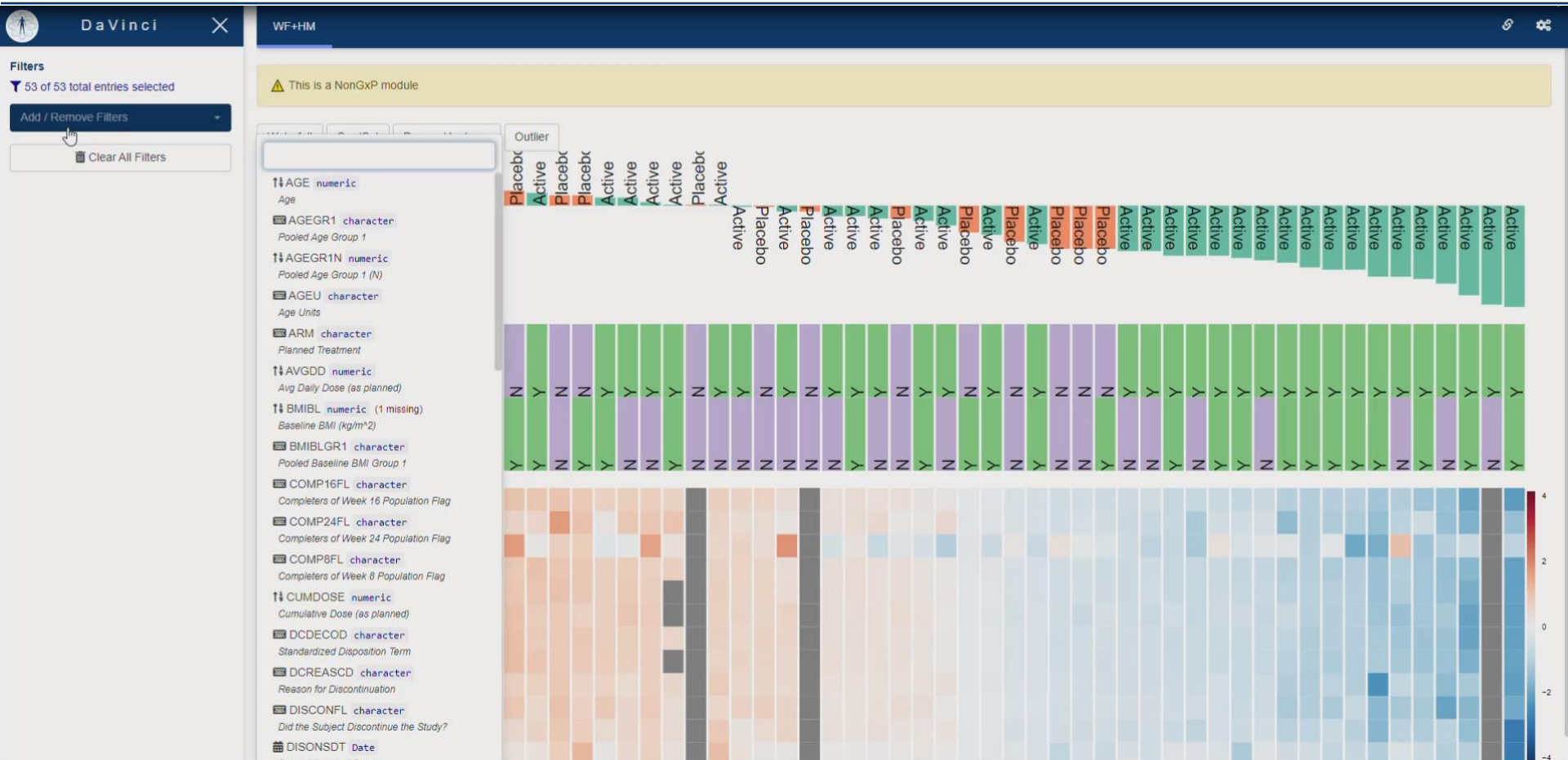

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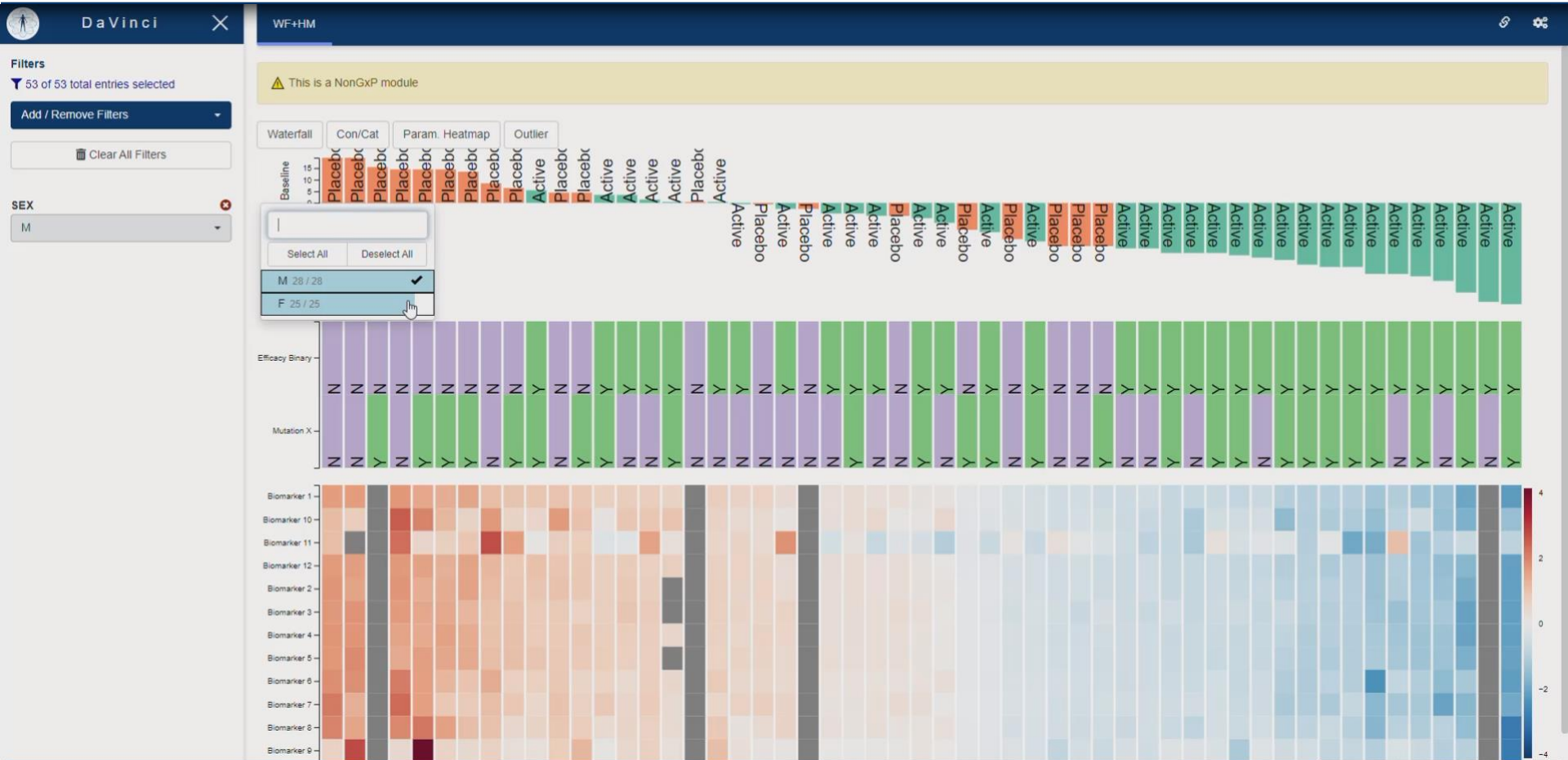
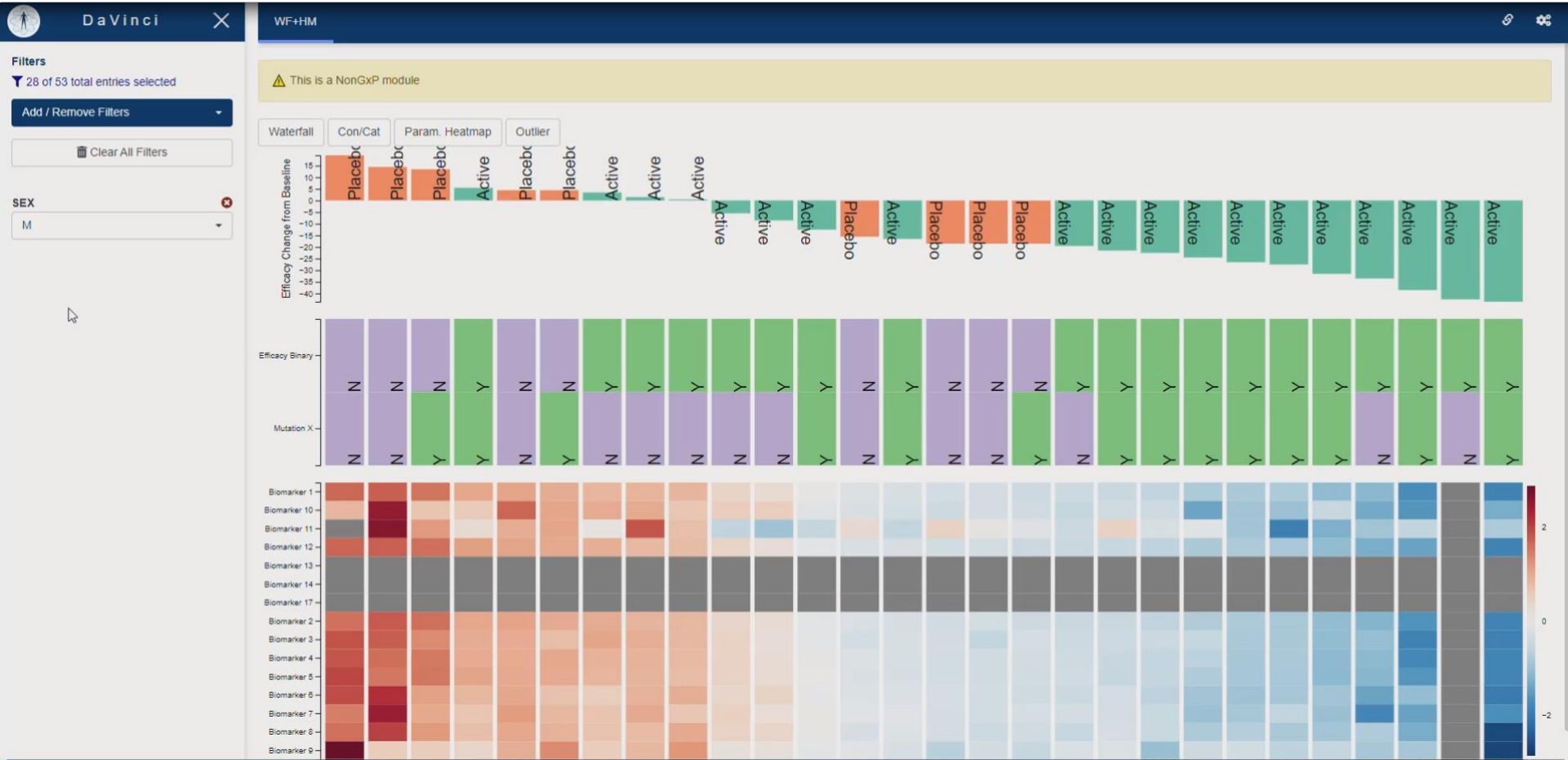
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