Boehringer Ingelheim

StatistiCs M NCE

Trending of (Ongoing) Stability Data

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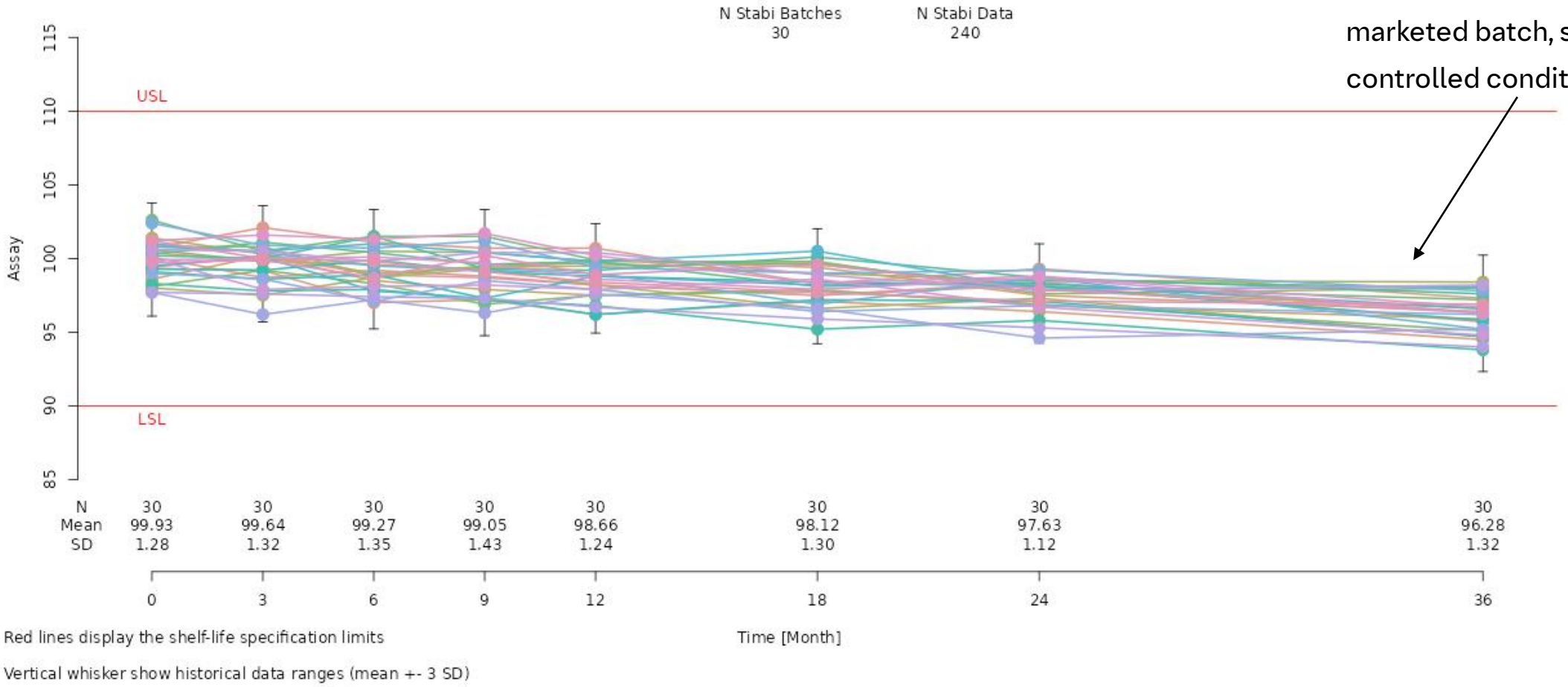
Life forward

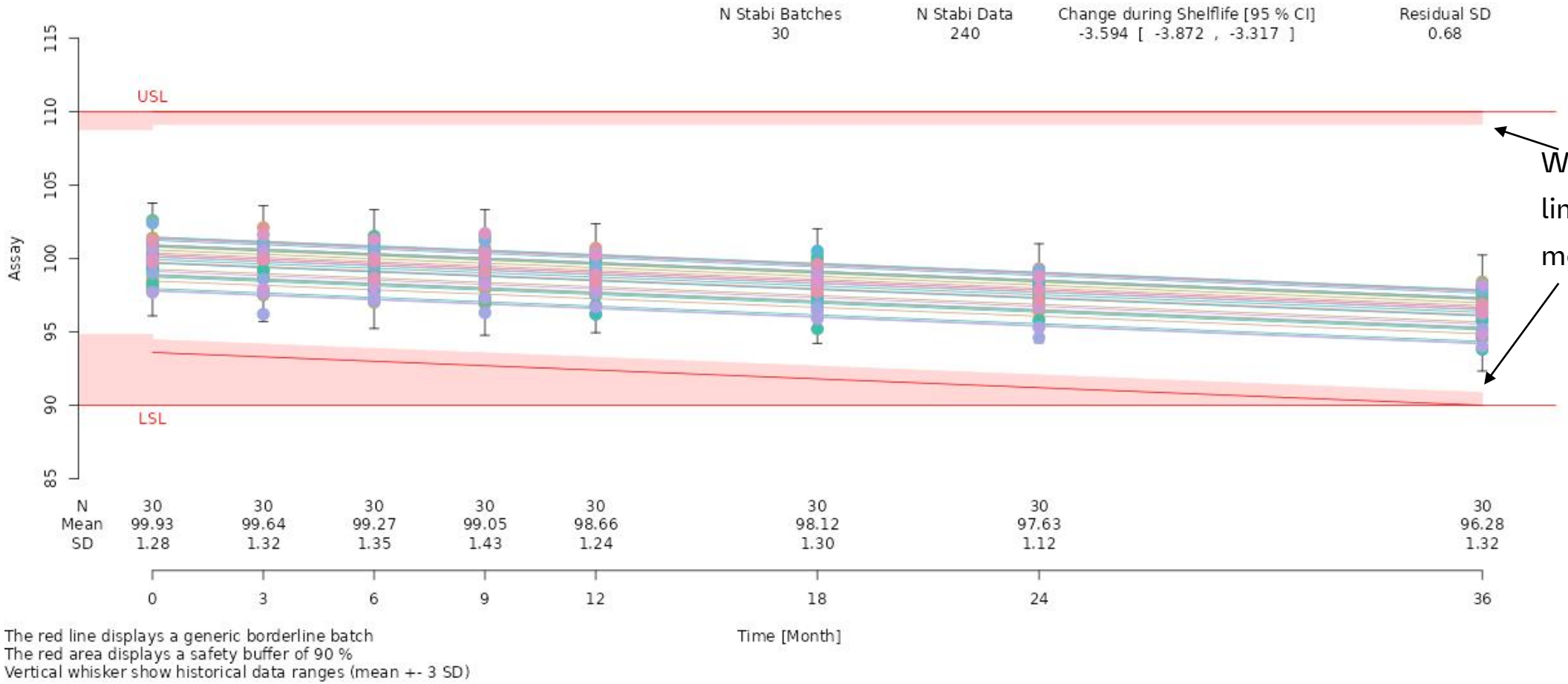
Ongoing Stability Data

Each series corresponds to a marketed batch, stored under controlled conditions



Objective: Early detection of trends leading to possible OOS values

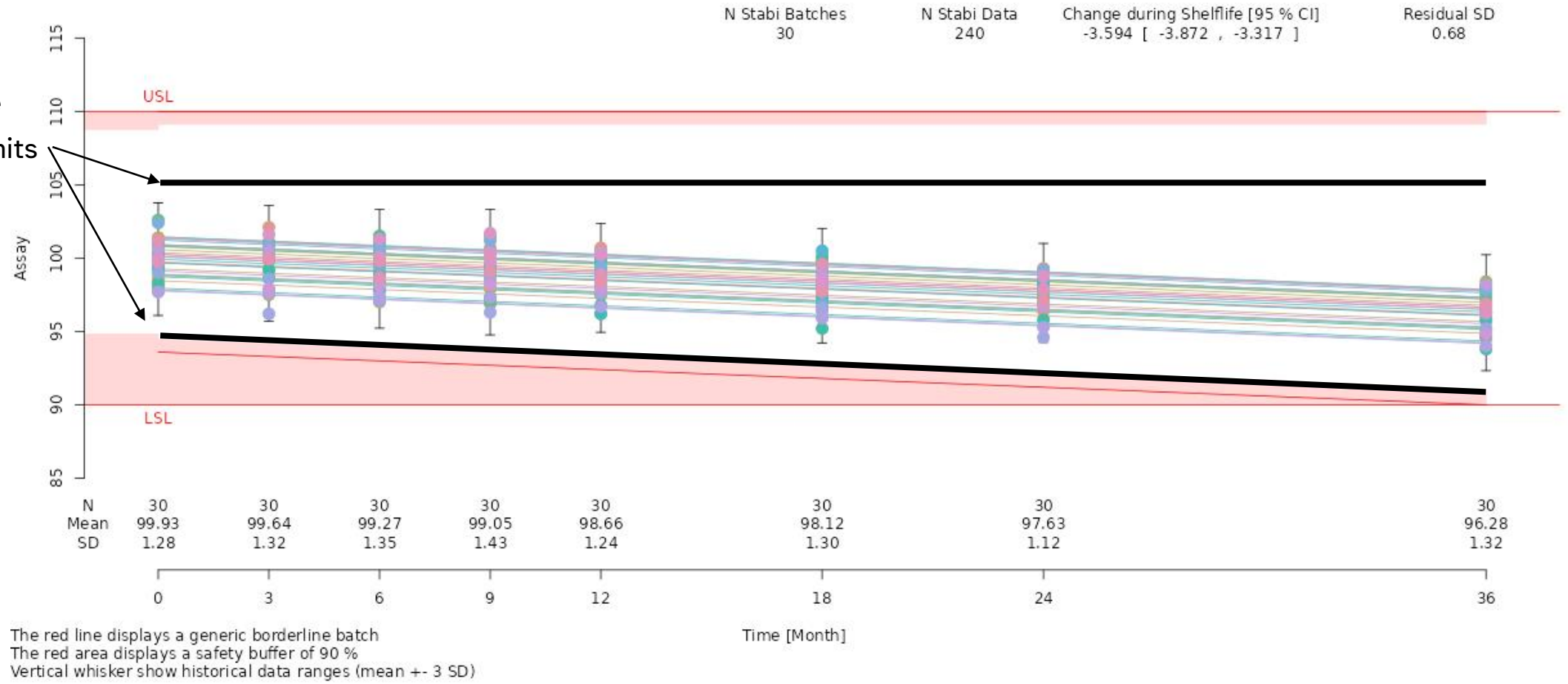
Derivation of Out-Of-Trend Limits



Widest possible limits (based on model)

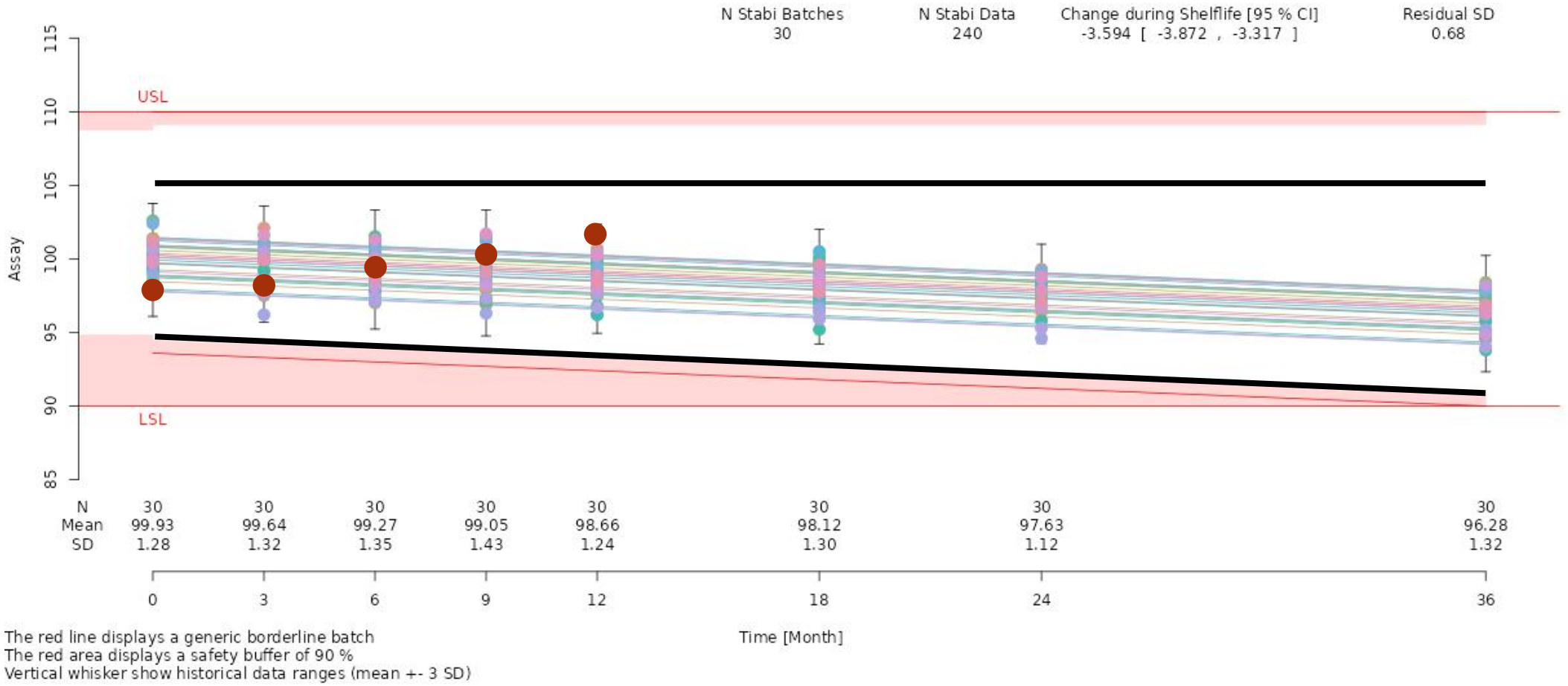
Derivation of Out-Of-Trend Limits

Possible OOT Limits



The red line displays a generic borderline batch
The red area displays a safety buffer of 90 %
Vertical whisker show historical data ranges (mean +- 3 SD)

Detection of atypical behavior



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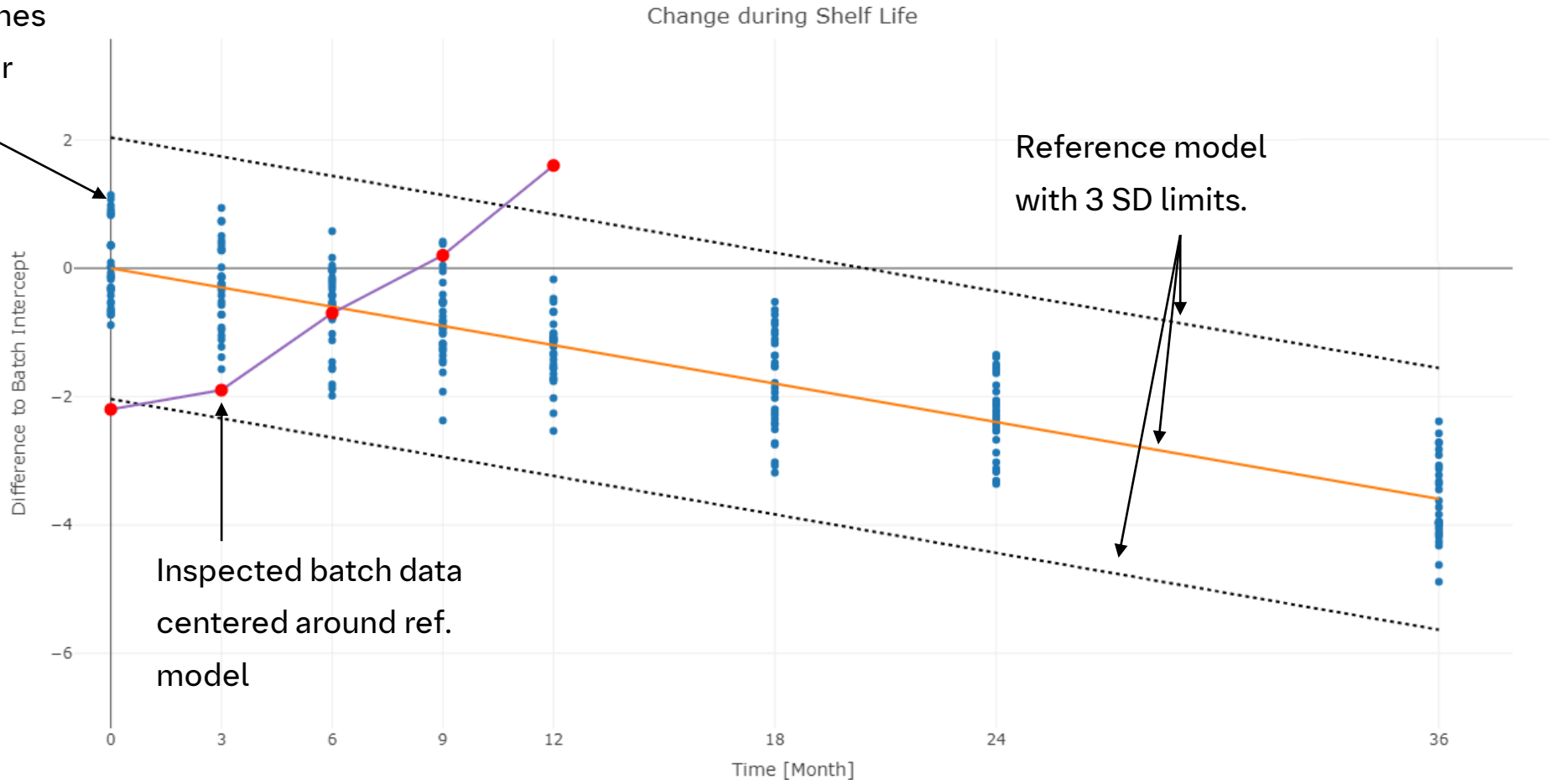
Detection of atypical behavior

Reference batches adjusted by their intercepts



Reference model with 3 SD limits.

Inspected batch data centered around ref. model

Automatic detection possible!

→ Single values as well as difference Last-First

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Detection of atypical behavior

A more sensitive test for atypical batches can be obtained by looking at the changes between two consecutive time points.

More precisely, consider the deviation of the observed change and the change predicted by a model (fitted to some reference data).

Values which are consistently above- or below the model prediction may be atypical.