A Modern Approach to Stability Studies via Bayesian Linear Mixed Models Incorporating Auxiliary Effects
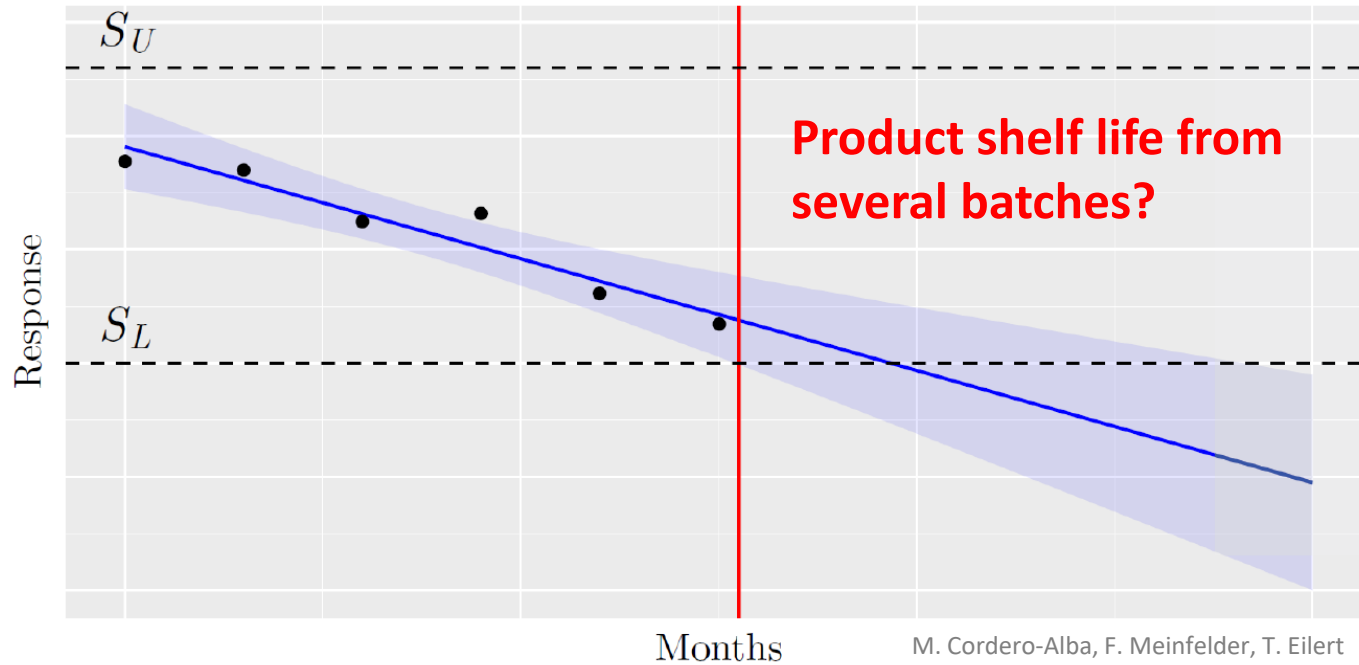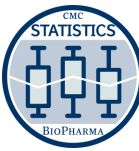
Tobias Eilert 26.10.2023

Product shelf life from several batches?
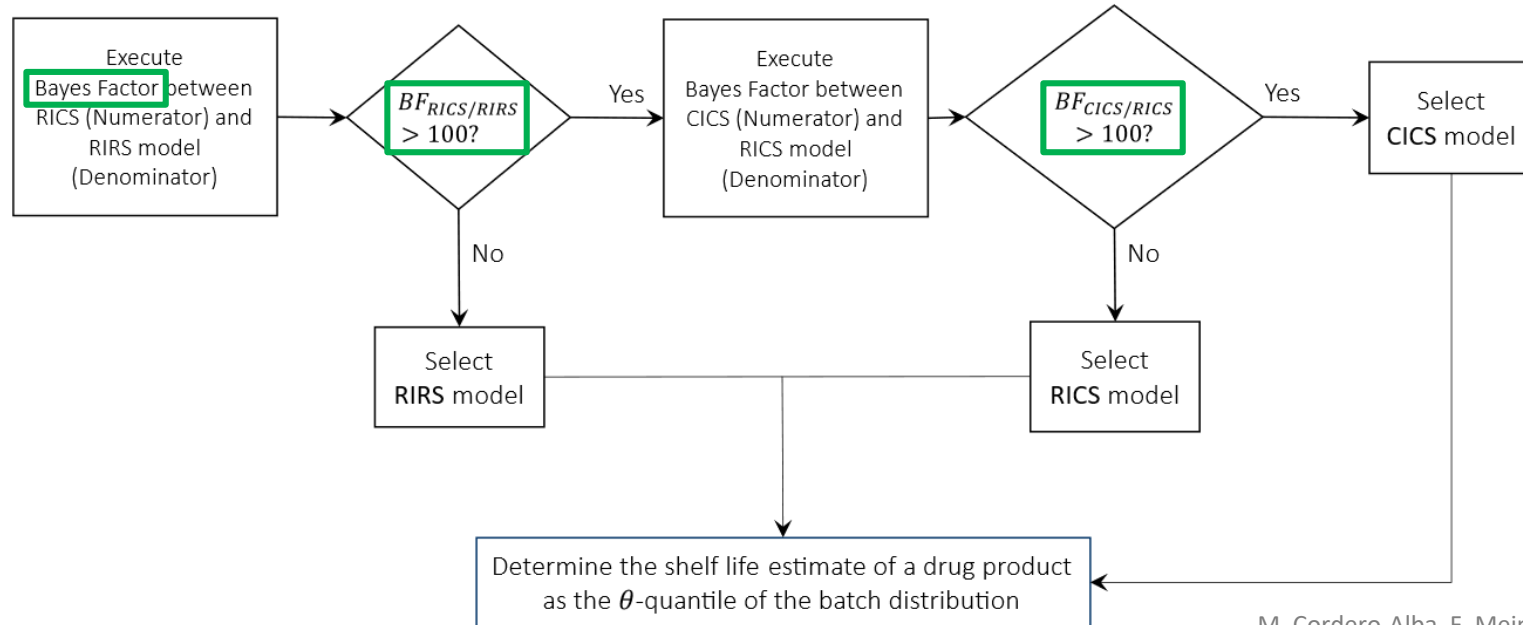
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Representing the ICH Q1E by a Bayesian LMM

Random Intercept & **Random** Slope (**RIR**S)

Random Intercept & *Common* Slope (**RIC**S)

Common Intercept & *Common* Slope (**CIC**S)

Execute Bayes Factor between RICS (Numerator) and RIRS model (Denominator)

$BF_{RICS/RIRS} > 100?$

Yes

Execute Bayes Factor between CICS (Numerator) and RICS model (Denominator)

$BF_{CICS/RICS} > 100?$

Yes

Select CICS model

No

No

Select RIRS model

Select RICS model

Determine the shelf life estimate of a drug product as the θ-quantile of the batch distribution

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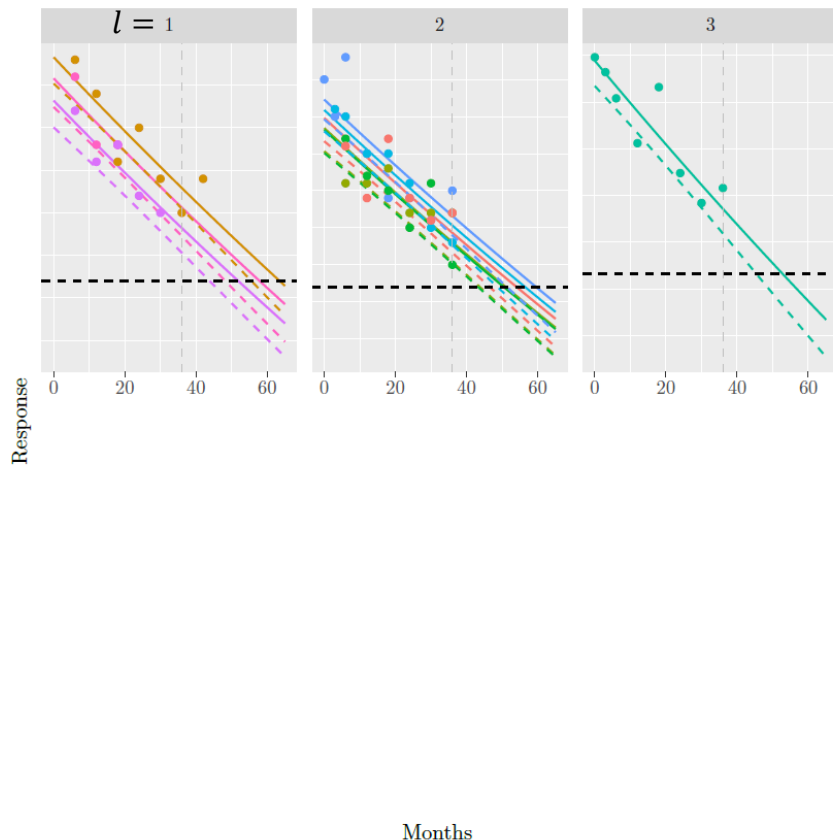
Boehringer Ingelheim

Case Study II: Results
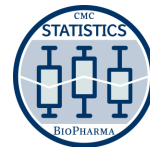
$$B_{tl} = C_l + \alpha_{jl} + \beta_0 t$$
$$\alpha_{jl} \sim \mathcal{N}(0, \sigma_\alpha)$$

Batch Shelf Lives:
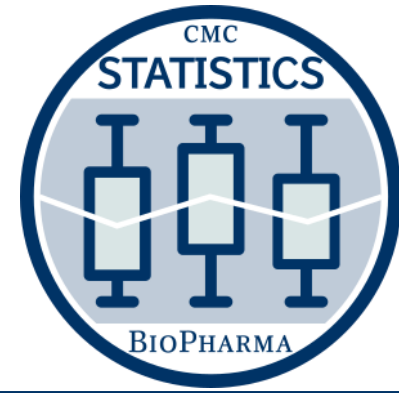
Batch	Concentration	$\hat{t}_S^{ICH}$
1	1	48.00
2	1	43.50
3	1	55.50
4	2	51.00
5	2	43.50
6	2	48.50
7	2	43.00
8	2	46.50
9	3	45.00

Product Shelf Lives:

Concentration	$\hat{t}_{S,l}^{ICH}$
1	43.50
2	43.00
3	45.00

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Thank you for your Attention!

Do you have any Questions, Comments or Remarks?