Quantitative Benefit-Risk

Jim Felli
Eli Lilly & Company

Quantitative BR

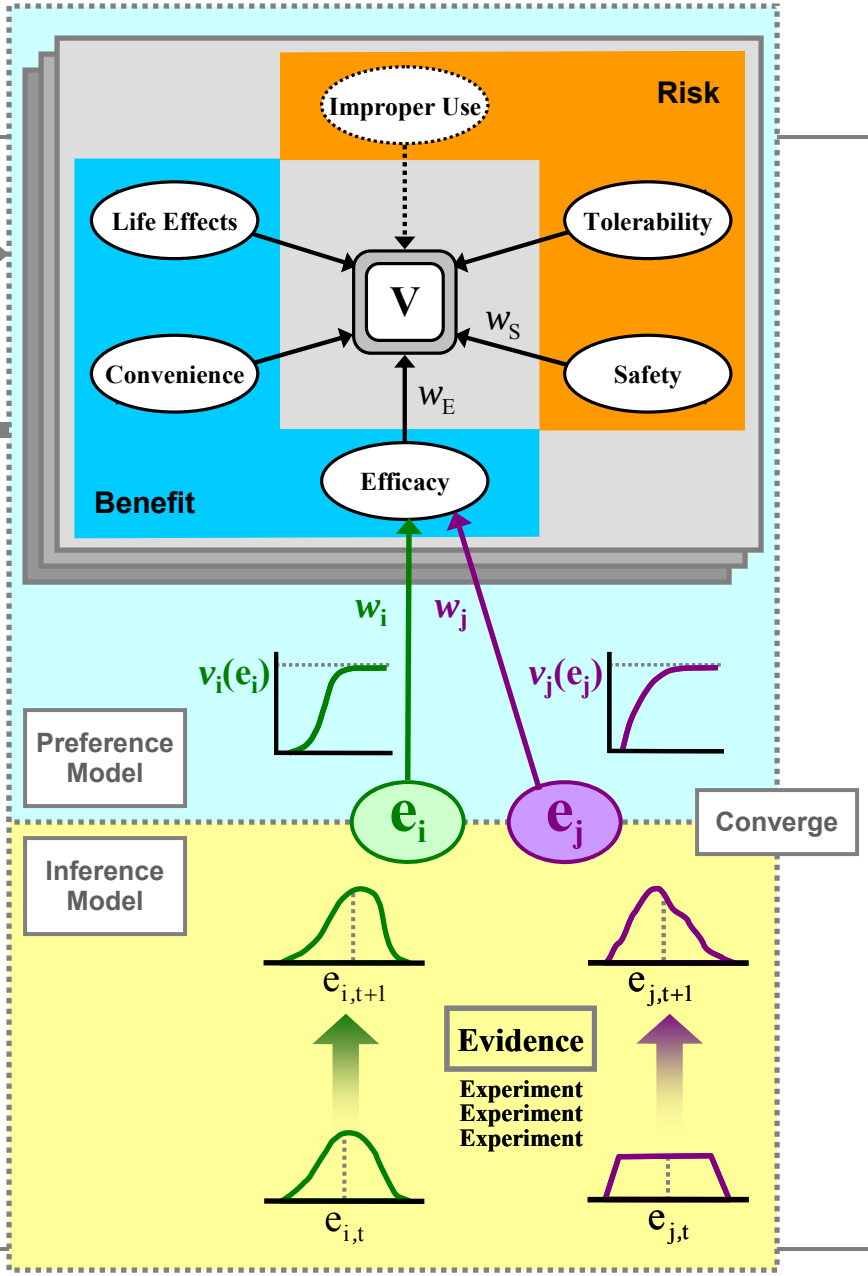
Lilly's quantitative benefit-risk model is:

- based on **multi-criteria decision analytic methods** (MCDA),
- a **compensatory** model (surpluses offset deficits),
- a **snapshot** in time and information state (readily updatable),
- a **transparent** representation of beliefs informed by **data** and **expertise**, not a reformulation, replacement or optimization of an existing health outcome metric,
- a **discussion generation tool**, not a decision making tool.

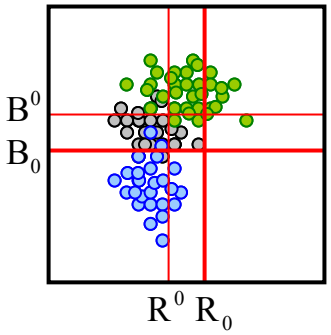
Quantitative BR

Frame

- Disease State
- Target Population
- Value Reference



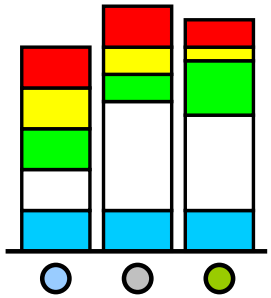
BRAM



$$B_a = \sum_{m \in M} \alpha_m v_m\left(x_m^a\right)$$

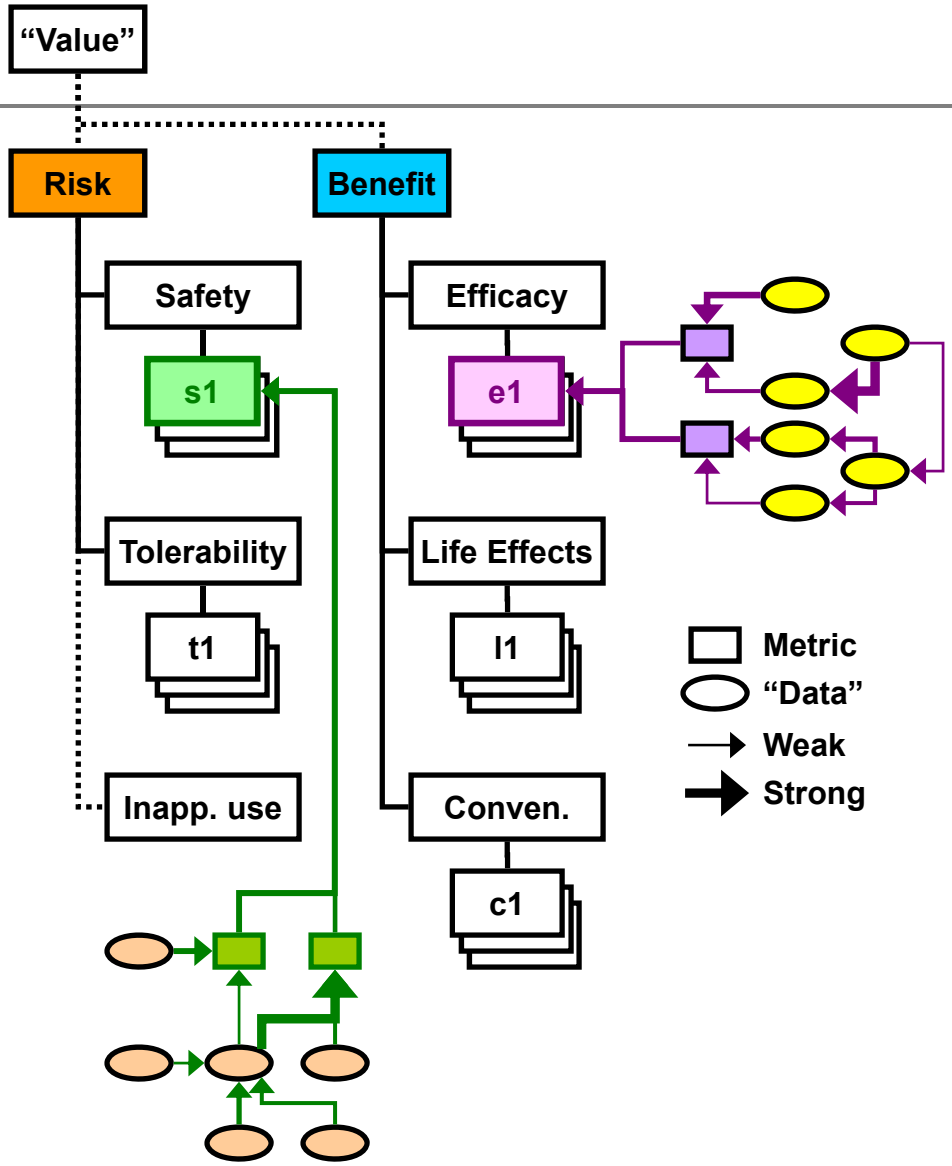
$$R_a = \sum_{n \in N} \beta_n \left[1 - v_n\left(x_n^a\right)\right]$$

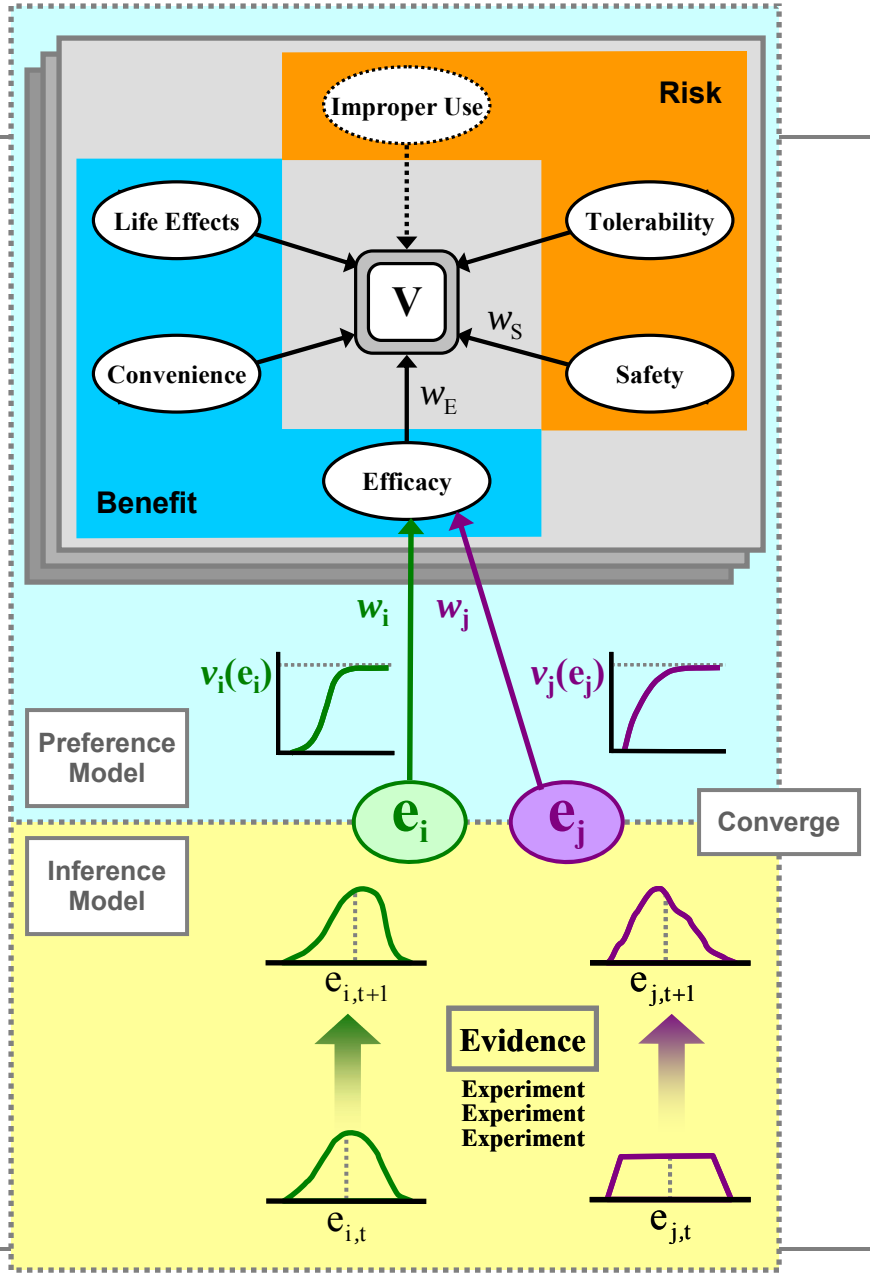
CUI



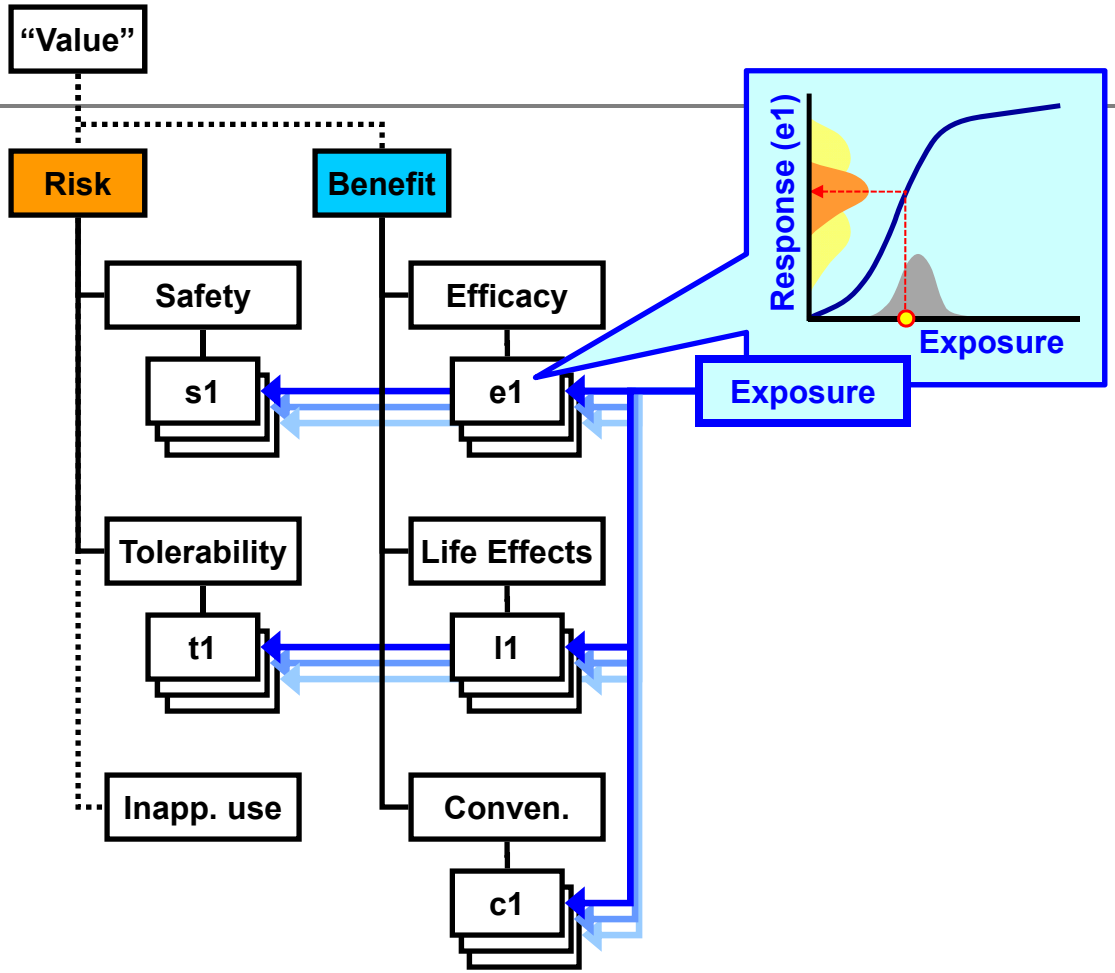
$$V_a = \sum_{k \in K} w_k v_k\left(x_k^a\right)$$

Quantitative BR

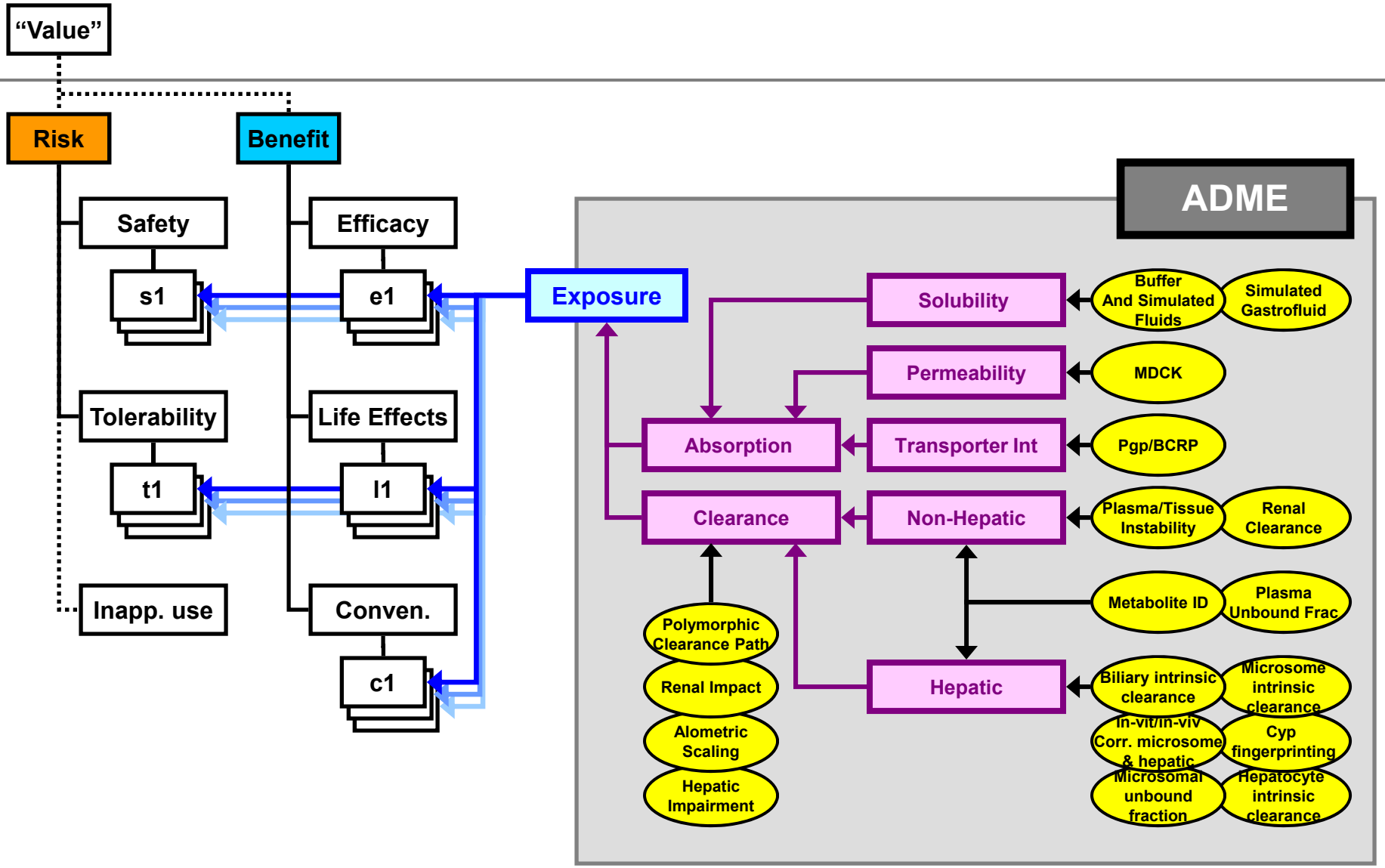




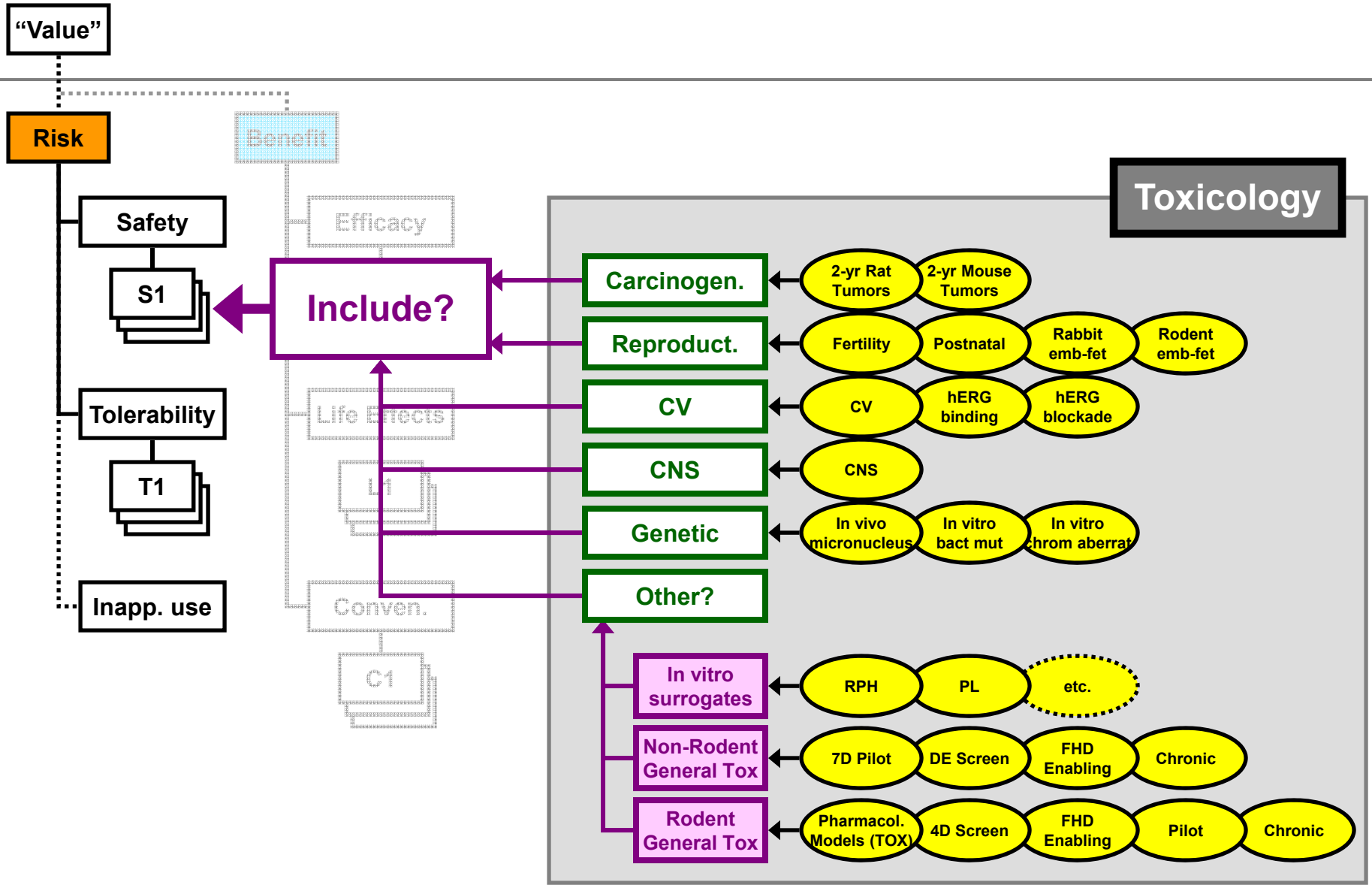
Quantitative BR



Quantitative BR



Quantitative BR



Quantitative BR

Perspective	W
Patient	1
Prescriber	0
Developer	0
Regulator	0
Payer	0

Analytic Focus
Benefit:Risk

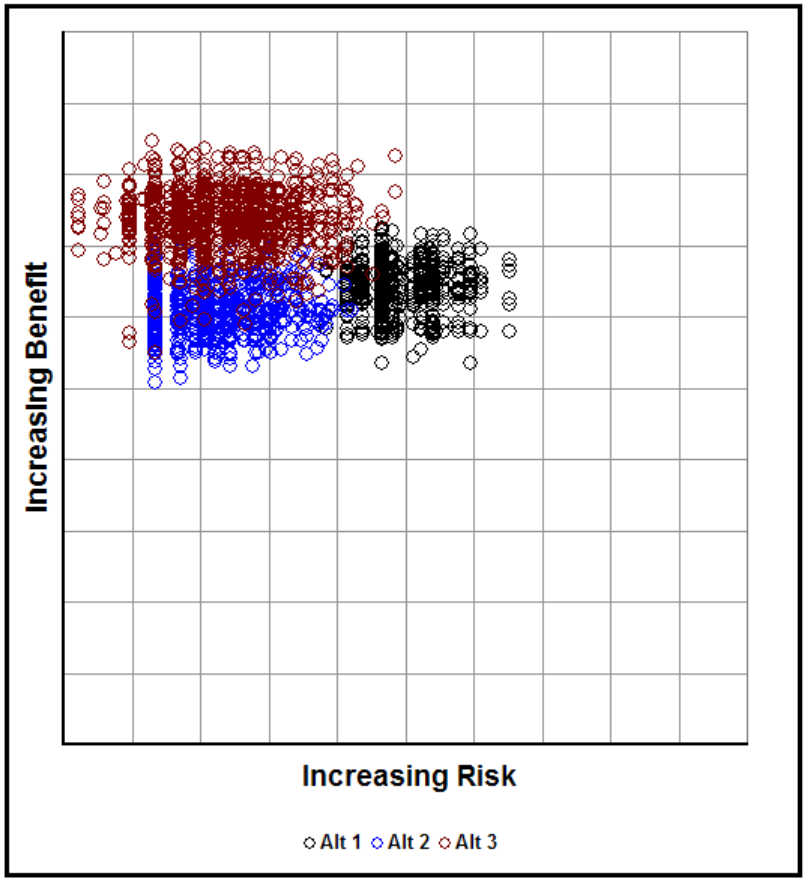
Data Set
(x,y) points

Graph Type
Profiles

Alternatives
Generic Names

No. of Profiles
1000

Alternatives
Alt 1
Alt 2
Alt 3



Alternatives	P[B+]	P[R-]	P[Opt]
Alt 1	0.027	0	0
Alt 2	0.011	0.622	0.0068
Alt 3	0.962	0.42	0.404

Quantitative BR

Perspective	W
Patient	1
Prescriber	5
Developer	1
Regulator	6
Payer	1

Analytic Focus
Benefit:Risk

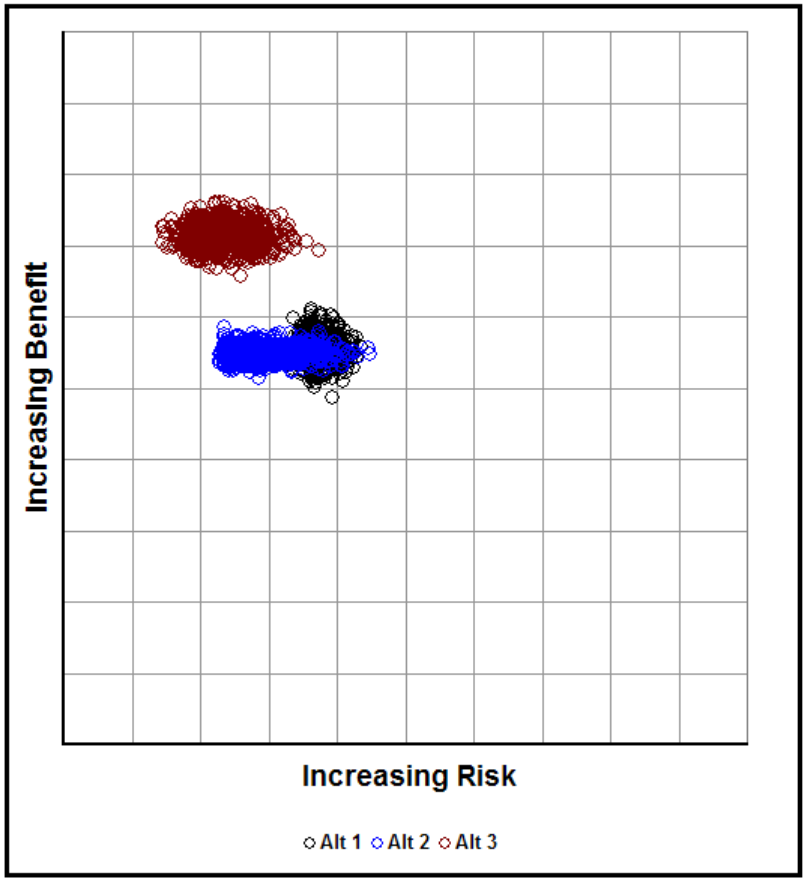
Data Set
(x,y) points

Graph Type
Profiles

Alternatives
Generic Names

No. of Profiles
1000

Alternatives
Alt 1
Alt 2
Alt 3



Alternatives	P[B+]	P[R-]	P[Opt]
Alt 1	0	0	0
Alt 2	0	0.132	0
Alt 3	1	0.868	0.868

Quantitative BR

Perspective	W
Patient	1
Prescriber	0
Developer	0
Regulator	0
Payer	0

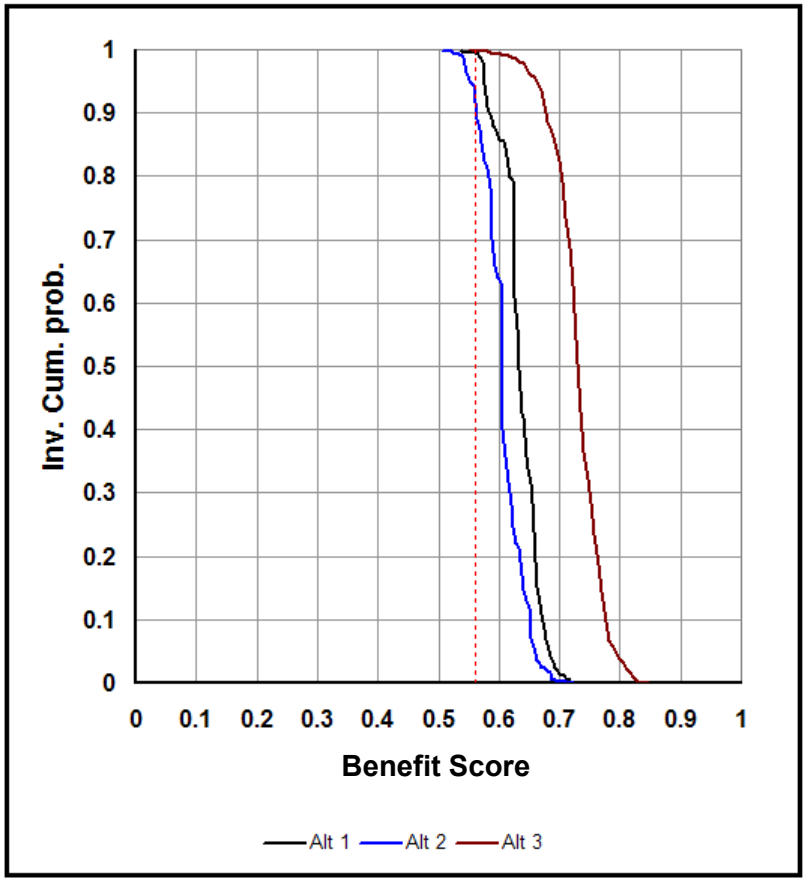
Analytic Focus
Benefit:Risk

Data Set
Positives

Graph Type
Inv. Cum. Distr.

Alternatives
Generic Names

Alternatives
Alt 1
Alt 2
Alt 3



Critical Score 0.56

Alternatives	P[>Crit]
Alt 1	0.995
Alt 2	0.942
Alt 3	0.999

Quantitative BR

Perspective	W
Patient	1
Prescriber	5
Developer	1
Regulator	6
Payer	1

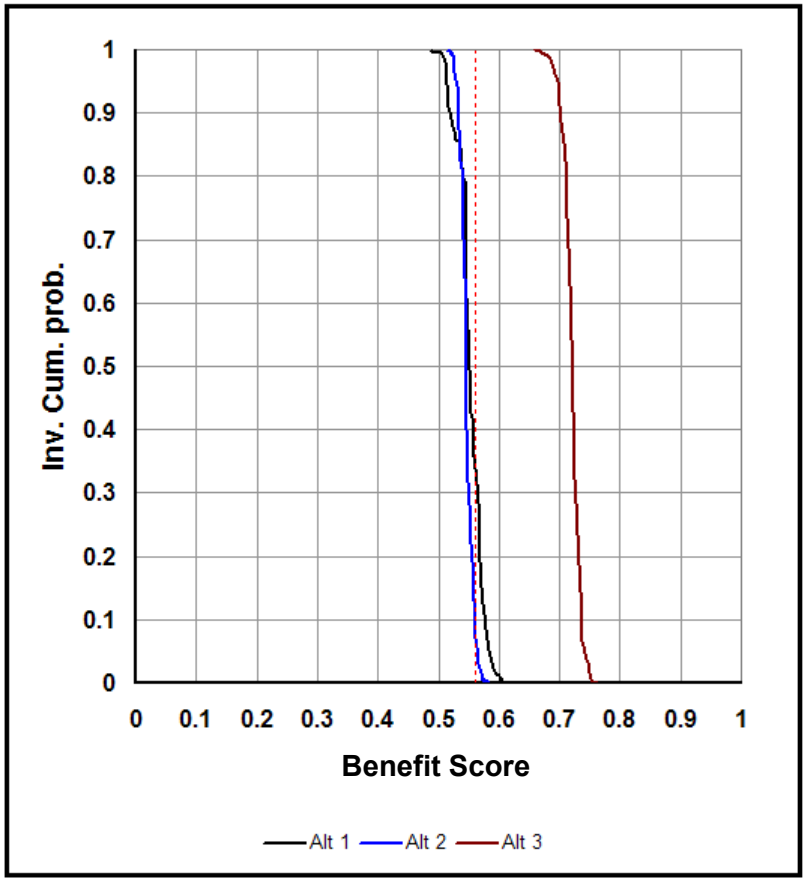
Analytic Focus
Benefit:Risk

Data Set
Positives

Graph Type
Inv. Cum. Distr.

Alternatives
Generic Names

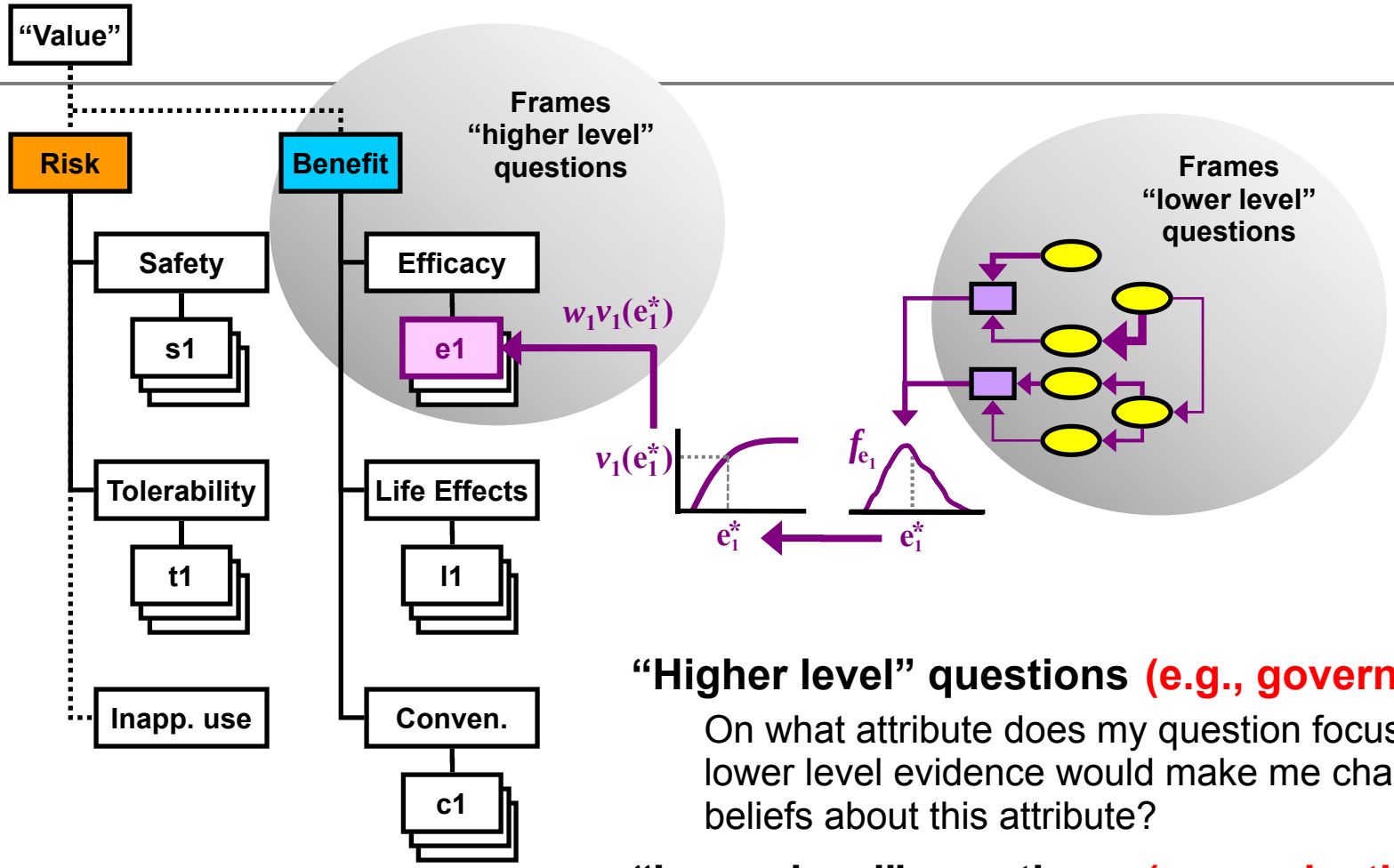
Alternatives
Alt 1
Alt 2
Alt 3



Critical Score 0.56

Alternatives	P[>Crit]
Alt 1	0.358
Alt 2	0.131
Alt 3	1

Quantitative BR



"Higher level" questions (e.g., governance)

On what attribute does my question focus? What lower level evidence would make me change my beliefs about this attribute?

"Lower level" questions (e.g., scientists)

Why do I care about this question? What beliefs about higher level attributes will the answer inform?

Quantitative BR

Lilly's quantitative benefit-risk model has been:

- designed to provide a common, organization-spanning **framework** for drug development,
- designed to drive informed **discussion**,
- extended to the **data** definition and collection level.

Quantitative BR

End