# visit Simulation Report

## visit package 2019-08-15

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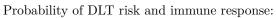
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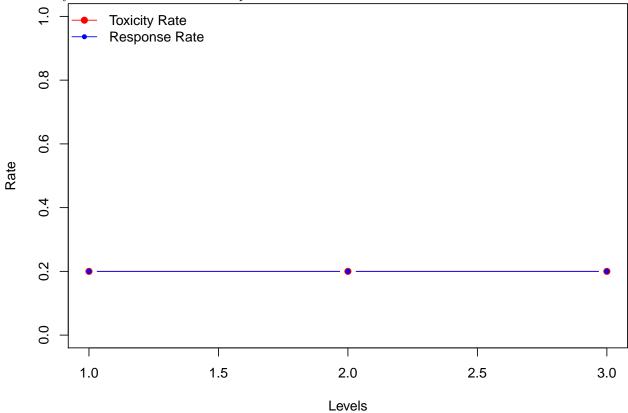
## Simulation Parameters

| Variables         | Values             |
|-------------------|--------------------|
| Number of doses   | 3                  |
| decision cuts     | 0.65,  0.65,  0.65 |
| etas              | 0.1,  0.3          |
| probability model | NONPARA            |
| cohort size       | 5                  |
| level size        | 10                 |
| n rep             | 100                |
| n core            | 3                  |

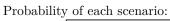
# Trueps Plots

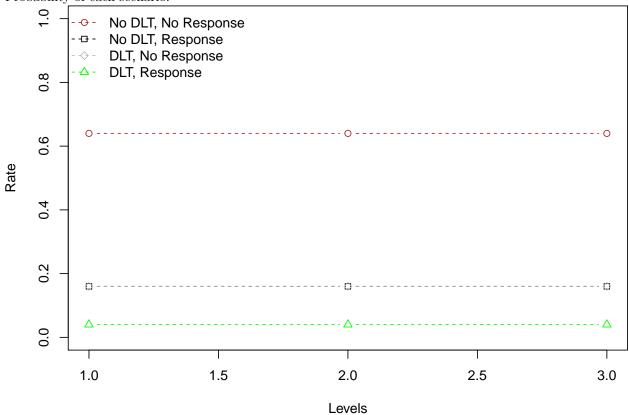
#### Trueps Plots 1





#### Trueps Plots 2





# Simulation Results

|           | 1     | 2     | 3     |
|-----------|-------|-------|-------|
| Frequency | 54.00 | 15.00 | 11.00 |
| %         | 54.00 | 15.00 | 11.00 |

|         | stage 1 | stage 2 | total |
|---------|---------|---------|-------|
| level 1 | 5.00    | 4.00    | 9.00  |
| level 2 | 4.00    | 1.75    | 5.75  |
| level 3 | 1.30    | 0.80    | 2.10  |

|                 | No T, No R | No T, R | T, No R | $_{\mathrm{T,R}}$ | ${ m T}$ | R    |
|-----------------|------------|---------|---------|-------------------|----------|------|
| level 1 stage 1 | 3.26       | 0.85    | 0.74    | 0.15              | 0.89     | 1.00 |
| level 1 stage 2 | 2.59       | 0.68    | 0.60    | 0.13              | 0.73     | 0.81 |
| level 1 total   | 5.85       | 1.53    | 1.34    | 0.28              | 1.62     | 1.81 |
| level 2 stage 1 | 2.55       | 0.55    | 0.76    | 0.14              | 0.90     | 0.69 |
| level 2 stage 2 | 1.08       | 0.31    | 0.24    | 0.12              | 0.36     | 0.43 |
| level 2 total   | 3.63       | 0.86    | 1.00    | 0.26              | 1.26     | 1.12 |
| level 3 stage 1 | 0.77       | 0.31    | 0.15    | 0.07              | 0.22     | 0.38 |
| level 3 stage 2 | 0.49       | 0.12    | 0.17    | 0.02              | 0.19     | 0.14 |
| level 3 total   | 1.26       | 0.43    | 0.32    | 0.09              | 0.41     | 0.52 |

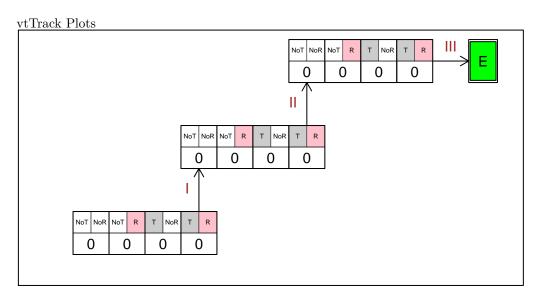
|                 | N      | Toxic | Ineffective | Safe, Effective | Effective, Safety concern |
|-----------------|--------|-------|-------------|-----------------|---------------------------|
| level 1 stage 1 | 100.00 | 20.00 | 0.00        | 0.00            | 80.00                     |
| level 1 stage 2 | 80.00  | 0.00  | 0.00        | 11.25           | 88.75                     |
| level 2 stage 1 | 80.00  | 33.75 | 22.50       | 0.00            | 43.75                     |
| level 2 stage 2 | 35.00  | 5.71  | 20.00       | 5.71            | 68.57                     |
| level 3 stage 1 | 26.00  | 26.92 | 11.54       | 0.00            | 61.54                     |
| level 3 stage 2 | 16.00  | 0.00  | 31.25       | 12.50           | 56.25                     |

|                 | Toxic | Ineffective | Safe, Effective | Effective, Safety concern |
|-----------------|-------|-------------|-----------------|---------------------------|
| level 1 stage 1 | 0.39  | 0.00        | 0.22            | 0.40                      |
| level 1 stage 2 | 0.23  | 0.00        | 0.24            | 0.54                      |
| level 2 stage 1 | 0.46  | 0.29        | 0.07            | 0.18                      |
| level 2 stage 2 | 0.26  | 0.29        | 0.13            | 0.32                      |
| level 3 stage 1 | 0.38  | 0.25        | 0.15            | 0.22                      |
| level 3 stage 2 | 0.23  | 0.33        | 0.13            | 0.30                      |

|                     | Mean | LB   | UB   |
|---------------------|------|------|------|
| level 1 stage 1     | 0.27 | 0.14 | 0.57 |
| level 1 stage 2     | 0.21 | 0.08 | 0.33 |
| level 2 stage 1     | 0.30 | 0.14 | 0.57 |
| level $2$ stage $2$ | 0.22 | 0.08 | 0.42 |
| level 3 stage 1     | 0.26 | 0.14 | 0.43 |
| level 3 stage 2     | 0.21 | 0.08 | 0.33 |

|                 | Mean | LB   | UB   |
|-----------------|------|------|------|
| level 1 stage 1 | 0.29 | 0.14 | 0.57 |
| level 1 stage 2 | 0.25 | 0.08 | 0.50 |
| level 2 stage 1 | 0.27 | 0.14 | 0.57 |
| level 2 stage 2 | 0.28 | 0.08 | 0.51 |
| level 3 stage 1 | 0.35 | 0.14 | 0.57 |
| level 3 stage 2 | 0.31 | 0.16 | 0.50 |

## Observation



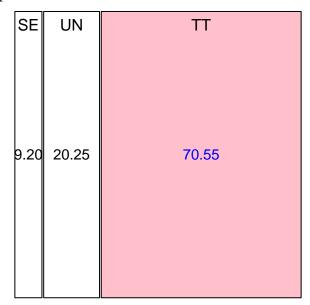
| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| 1 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 | 0 |
| 3 | 0 | 0 | 0 | 0 |

## Observation Interim

##

## Level 1

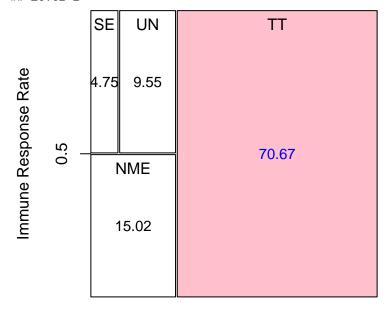
Immune Response Rate



**DLT Risk** 

##

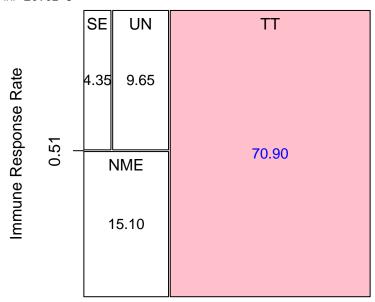
## Level 2



**DLT Risk** 

##





DLT Risk