Design:

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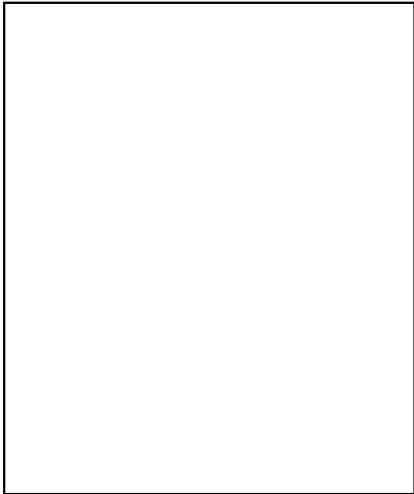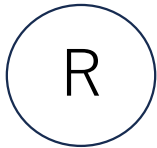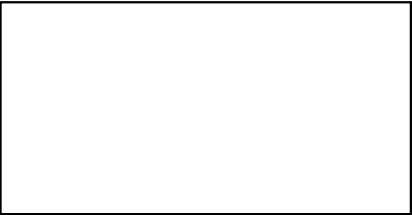
R

O

Primary endpoint

Secondary endpoint