

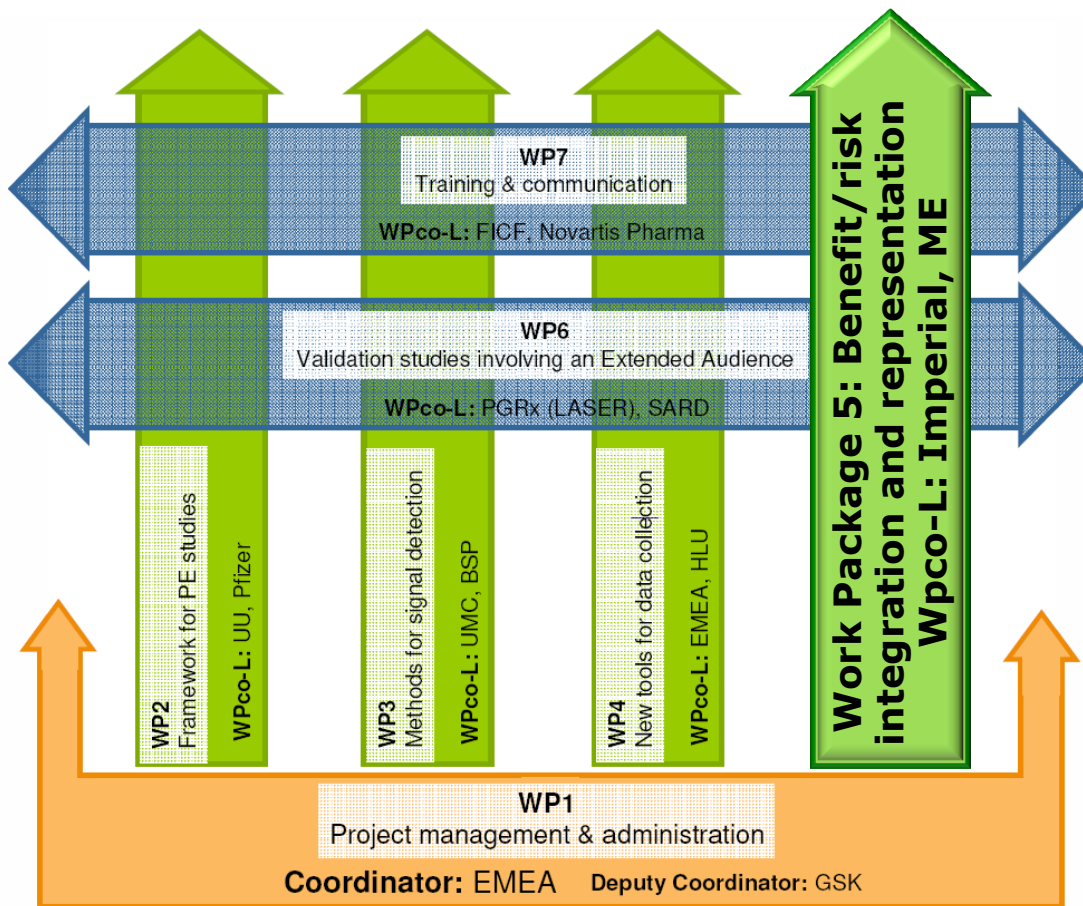
# PROTECT – WP5/WP6

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- Extension /Validation of Benefit-Risk Methods, Tools and Processes Evaluated in PROTECT- WP5

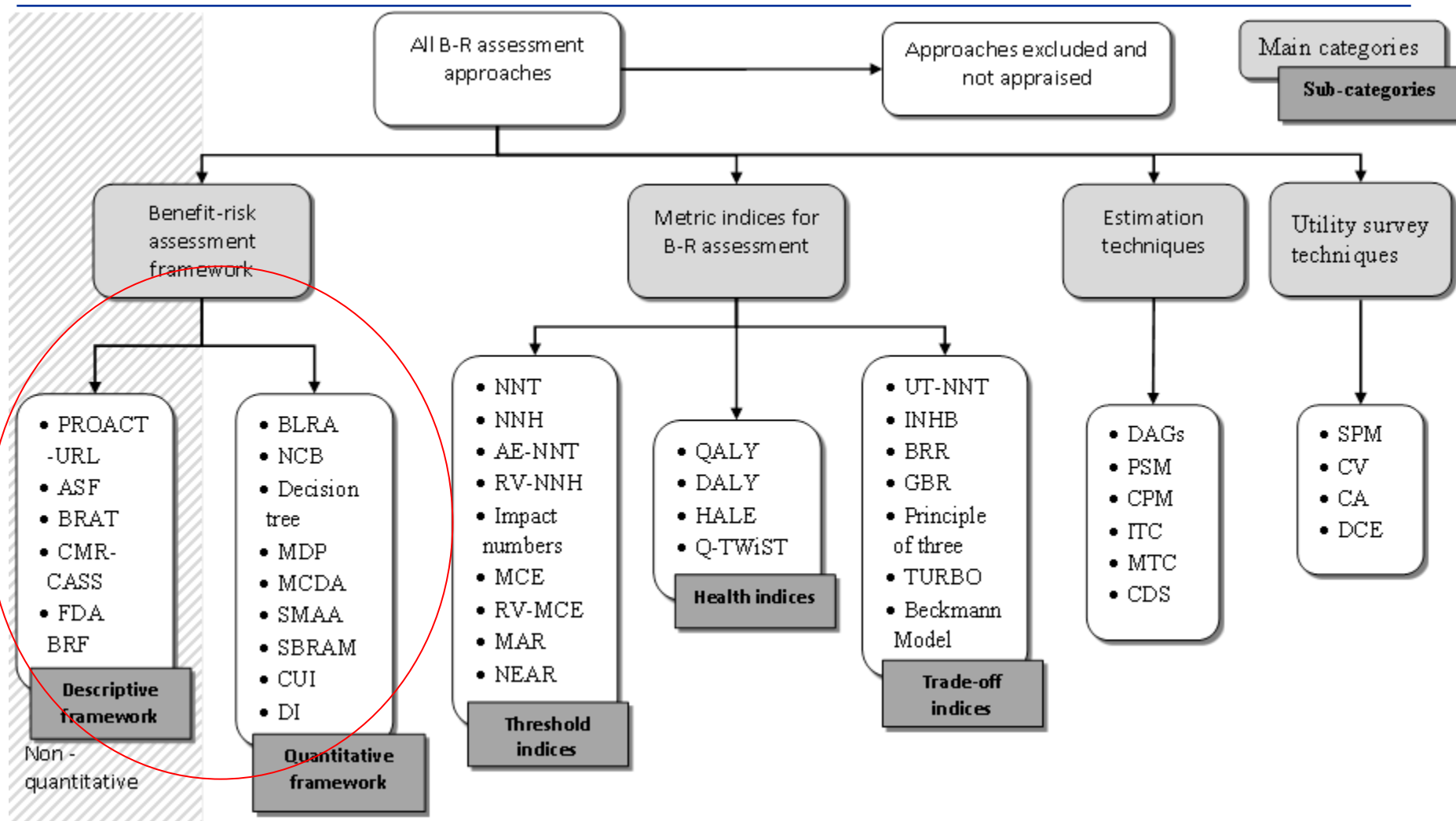
Presented by: Andrea Beyer, EMA

# PROTECT- Work Package Overview



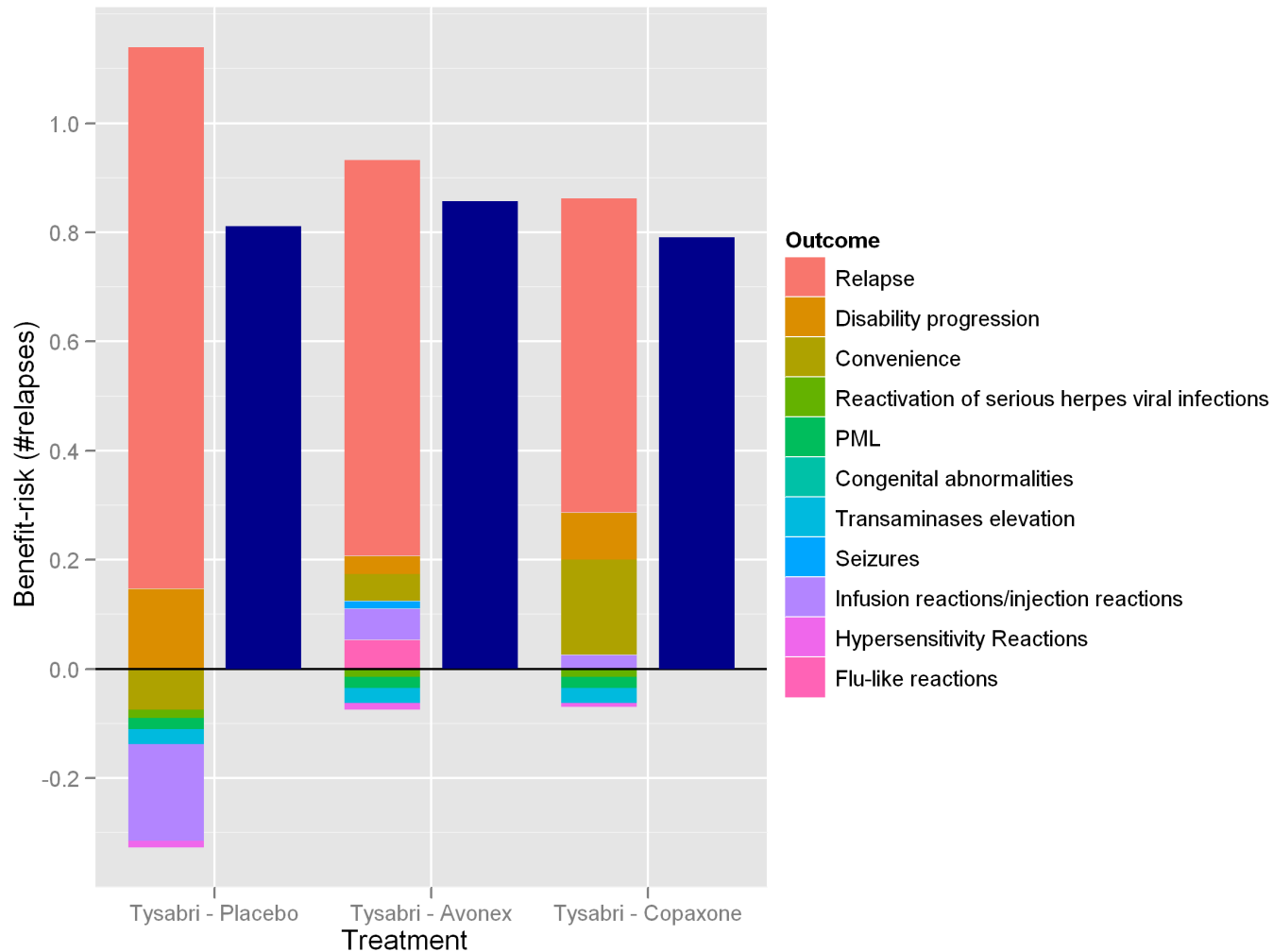
- One WP concerned with all aspects of the organisation and management of PROTECT
- Four “vertical” WPs targeting the specific objectives and methodological developments
- Two “horizontal” WPs concerned with the communication, validation and integration of the scientific work into an integrated and cohesive European activity

# WP5- Benefit-Risk Methodologies



## Tysabri: MCDA criteria contribution

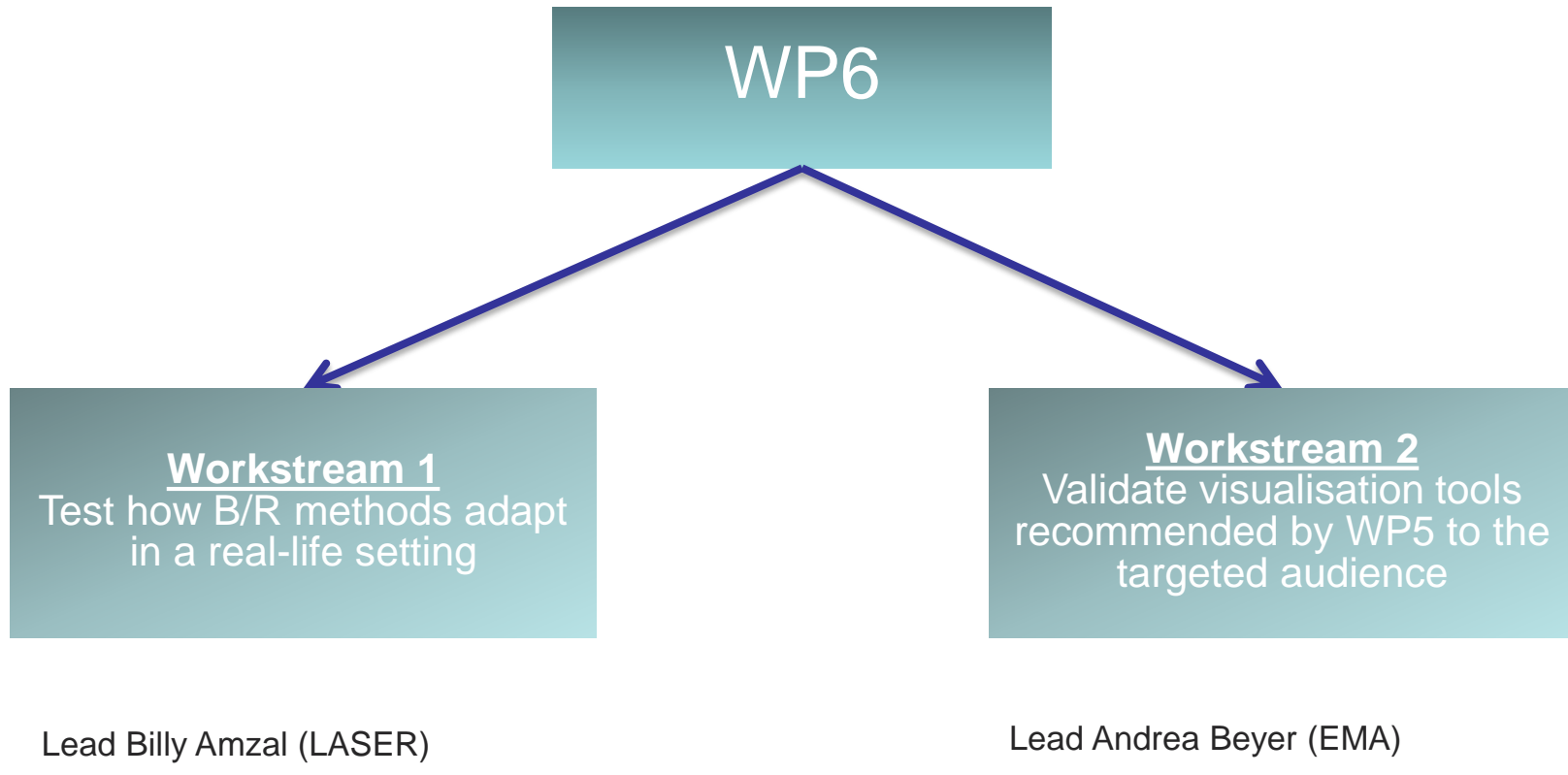
Stacked bar chart for Tysabri vs. all the other treatments.



- Same information shown as a stacked bar chart.
- Positive incremental benefit-risk components above the x-axis and negative ones below.
- Total benefit-risk shown as the dark blue bar.

## WP5/WP6 activities

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# Patients/HCP/ Regulators

Perception

Measure dimensions of benefit and risk perception

Visual presentation of data

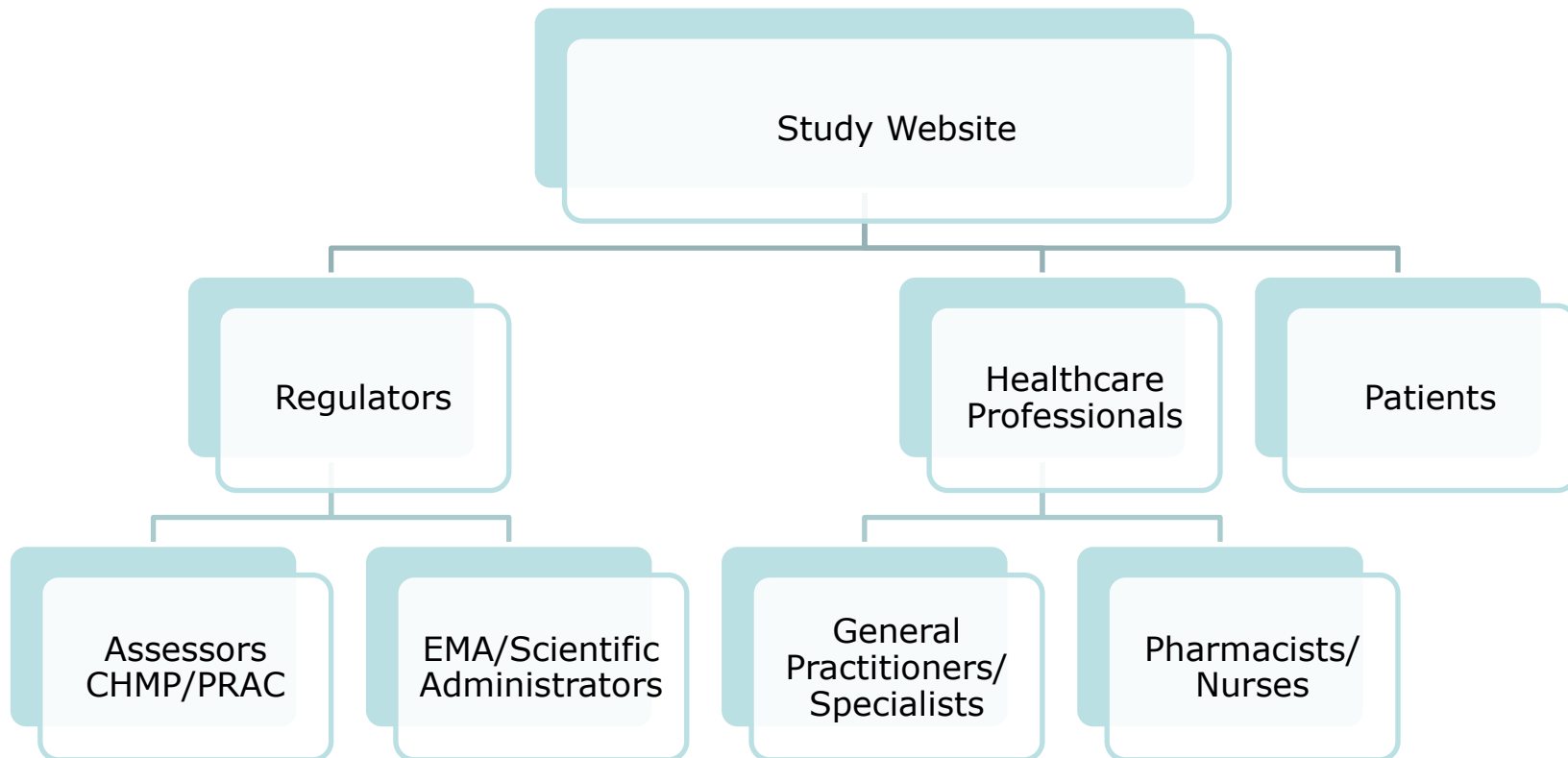
Visual presentation of benefit and risks using textual, tabular and other graphical formats

Elicitation of preferences for treatment outcomes

Discrete Choice Experiment

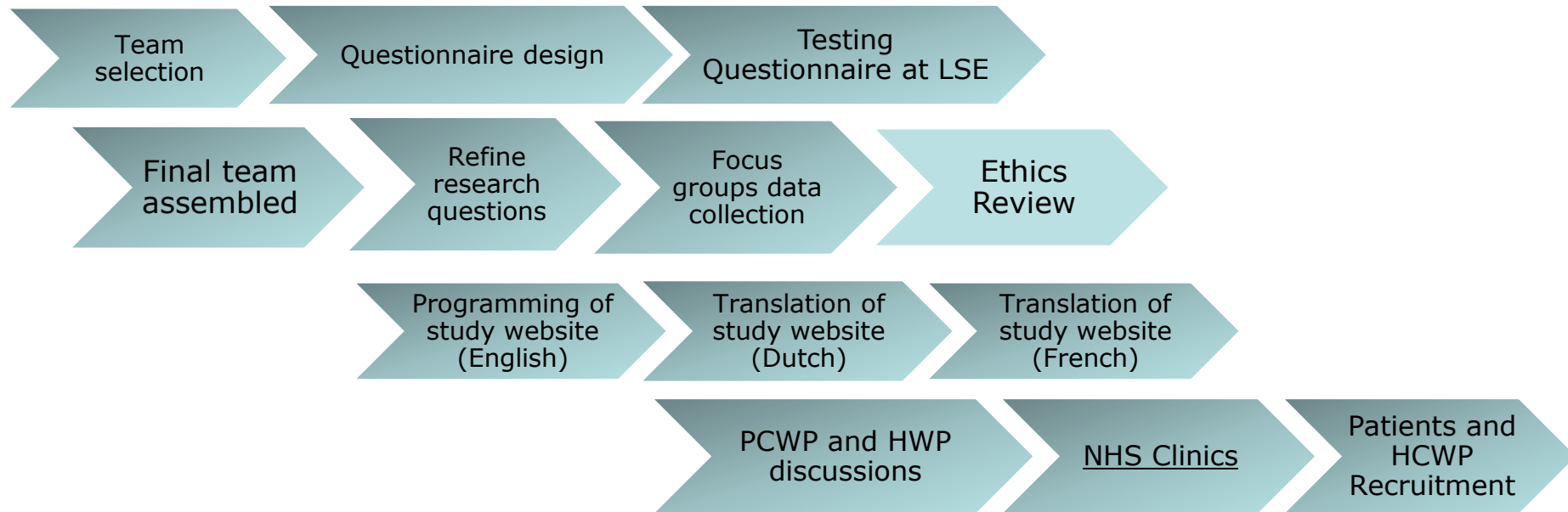
MCDA - MACBETH

# Data Collection – UK, France, the Netherlands



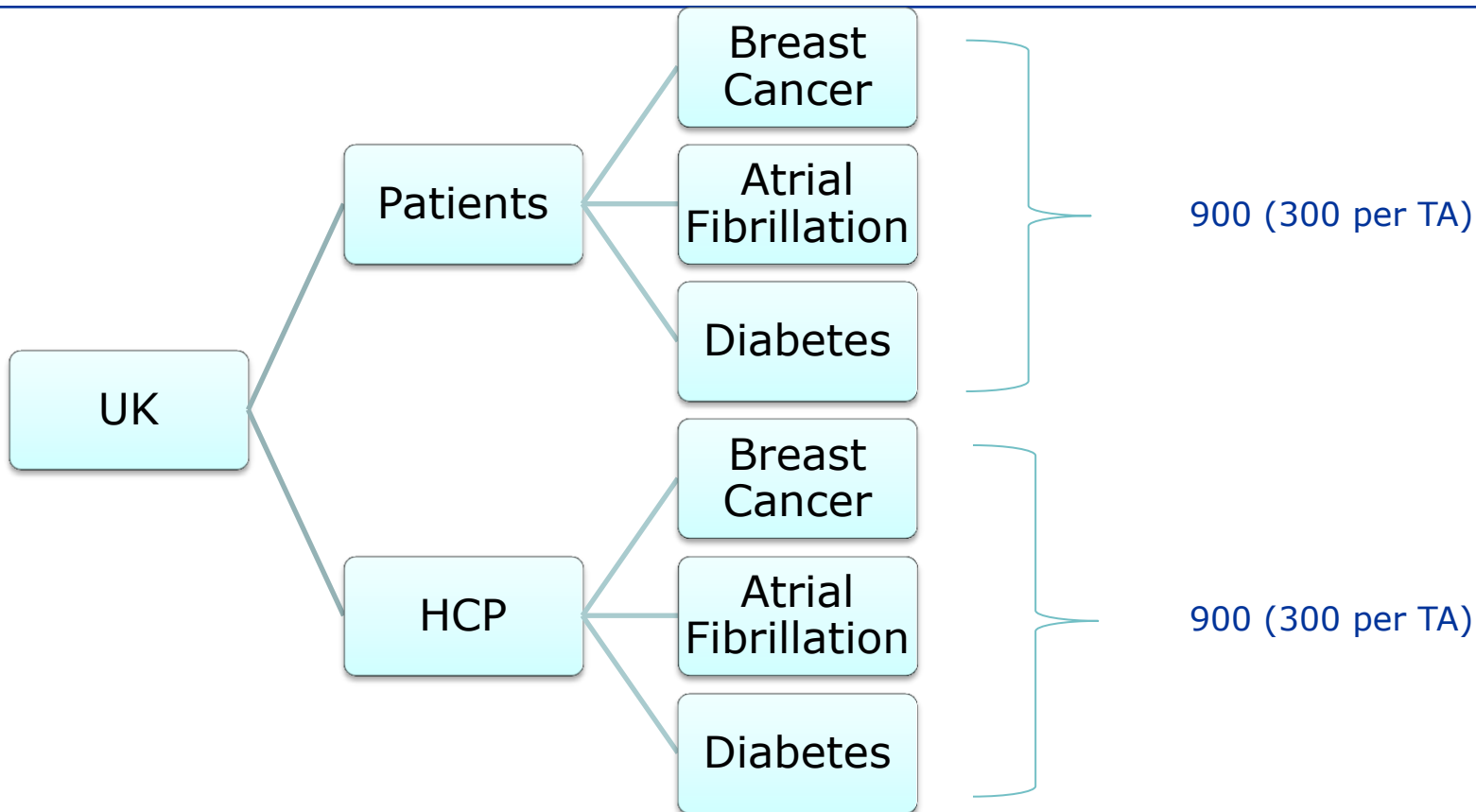
# Timeline/Deliverables 2013

March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
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# Participant Disposition



**5400 Patients and Healthcare Professionals across 3 countries (plus Regulators)**

# Thank You for Your Support!

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