Regulatory and HTA Engagement in Neurodegenerative Disease Research: A Decision Tool

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Background

Timely and effective engagement with regulatory and HTA agencies on evidence requirements is essential to ensure their requirements are included in the evidence development strategy to support new treatments.

This is particularly relevant in the area of neurodegenerative disease, for which despite high levels of research investment, there remains a lack of effective treatments.

Neuronet aims to address this challenge for a portfolio of Innovative Medicines Initiative (IMI) neurodegeneration projects (n=15) (Table 1, Figure 1).

Results

The majority of IMI neurodegeneration project outputs fall into the very early stages of research and development (Figure 2).

We developed a tool that helps identify the key opportunities to engage with EU regulatory and HTA agencies at key timepoints during the development of an 'asset'.

Table 1. IMI ND Portfolio

IMI Project	Dates
ADAPTED	2016 – 2019
AETIONOMY	2014 – 2018
AMYPAD	2016 – 2021
EMIF	2013 – 2018
EPAD	2015 – 2019
EQIPD	2017 – 2020
IM2PACT	2019 – 2023
IMPRiND	2017 – 2021
MOPEAD	2016 – 2019
PD-MitoQUANT	2019 – 2022
PHAGO	2016 – 2021
PRISM	2016 – 2019
RADAR-AD	2019 – 2022
RADAR-CNS	2016 – 2021
ROADMAP	2016 – 2018

The tool shows the relevant informal and formal processes and procedures for engagement based on the stage of research and 'asset' being developed.

Figure 1. Neuronet Project Disease Profile

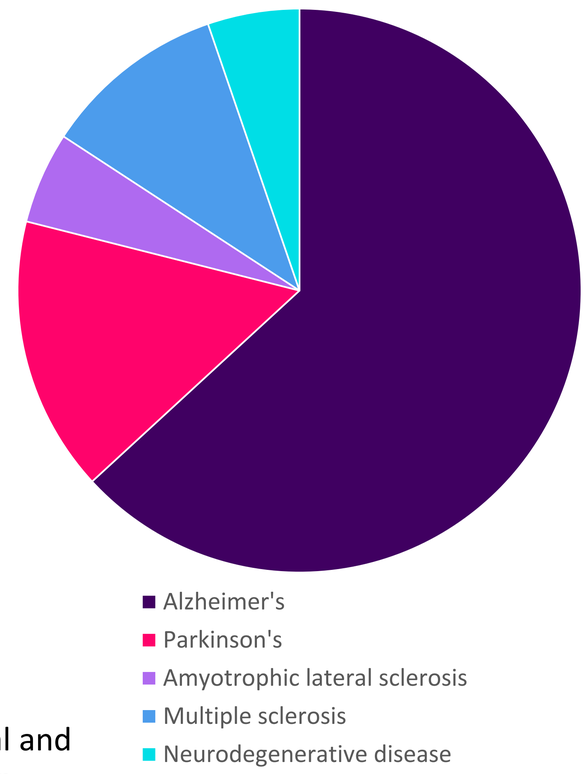
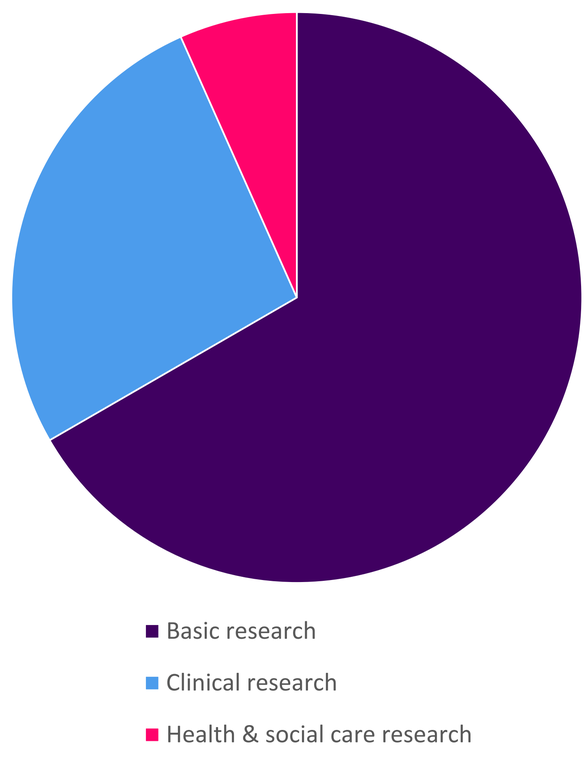
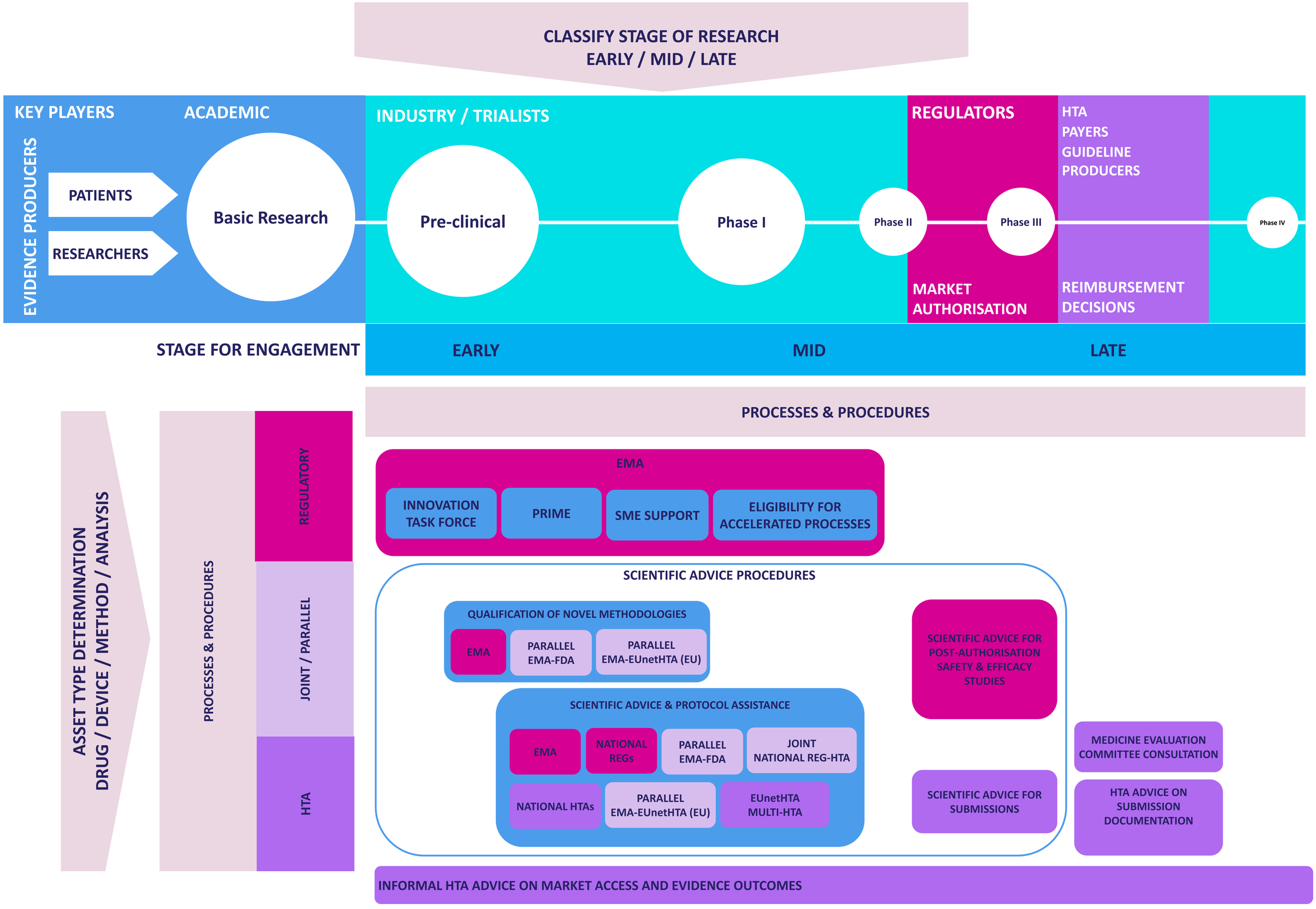


Figure 2. Neuronet Project Research Classification



RELEVANT APPROACH FOR ENGAGEMENT



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