

# AMBITION: Establish value demonstration at the heart of development strategy and evidence generation

## LABEL DRIVEN DEVELOPMENT

- Focus on regulatory needs (TPP)
- Focus on the conventional set of RCTs for registration
- RCT delivery an ongoing concern
- Assumes that modelling can address evidence gaps
- RWE\* = post launch registry
- Value will be obvious to the experts



## VALUE DRIVEN DEVELOPMENT

- Begins with “What are the unmet needs of patients and the healthcare system?”
- What evidence standards do different stakeholders require?
- Can RCTs address the unmet needs in terms of population and outcomes?
- What else needs to be done pre-launch alongside RCTs (PCT/ RLS, RWE, Models)?
- How soon can further evidence be delivered post launch (cross-country)?
- What trade-offs are possible to arrive at an optimal scenario (value and evidence required)?

\*RWE = Real World Evidence

# Target Value Proposition: Summary of the value story and key evidence claims that a new product would need to demonstrate to payers, policy makers, and prescribers (and at times, vaccinee); whether in the label; or built up from analysis of trials, RWE, patient outcomes research and modelling

<b>For (Populations of interest)</b>	[Target population]	<ul style="list-style-type: none"> <li>Indication, place in care pathway, other characteristics defining target subgroup/s</li> </ul>	
<b>Who (need)</b>	[Customer need]	<ul style="list-style-type: none"> <li>Population/s of interest, defined in terms of Unmet Need: e.g. high risk factors or recent poor outcomes.</li> </ul>	<ul style="list-style-type: none"> <li>Summary statement of the nature of the value delivered by the product: e.g. the first... the best...</li> </ul>
<b>Our product is / ambition</b>	[Characterisation of Project]		
	<b>Prescribers</b>	<b>Patients</b>	<b>Payors</b>
<b>That will Deliver</b>	<ul style="list-style-type: none"> <li>Descriptive: Most relevant “value statements” that will resonate strongly with all of the three stakeholder groups</li> </ul>		
	<ul style="list-style-type: none"> <li>Descriptive: additional elements of value that will resonate strongly with specific stakeholder groups</li> </ul>		