Joint Access Advisory Mechanism Candidate Presentation Checklist

	Please check when information is available √
DOCUMENTS REQUIRED FOR SUBMISSION	
JAAM submission document outlining bellow points	
- Name of compounds, developer	
- Background /rationale	
- Summary of compound; ingredient, dose, form, manufacturing, stability	
- Preclinical efficacy (in vivo, in vitro)	
- Preclinical safety (toxicology, preclinical pharmacology)	
- Pharmacokinetics/ ADME/ drug interaction	
- Lists of relevant clinical trials with sponsors' name	
- Clinical efficacy	
- Clinical safety (including post marketing safety information if drug is intended to be repurposed)	
- Clinical trial plan	
- Regulatory discussion – *if it exists*	
- Budget	
- Relevant publication	
IB or IMPD **If the IB has information, please identify the page as a reference*	
PREPARATION FOR DISCUSSION WITH JAAM	
What is the target disease?	
Can you clarify the target study population (severity, age groups, comorbidities, etc.)?	
Is this drug repurposing or Investigational New Drug?	
Can mechanism of action of the compound be well explained?	
Can you explain the Intervention – route of administration and dosing?	
Can you show the outline data of the preclinical and Phase I/II studies?	
Can you present the highlights of safety data if there are?	
Are there any additional outcomes of interest that you would like to explore?	
Are there any potential interest for public health (estimated cost per dose, accessibility, etc.)?	
Can you give us the information if preliminary contact been established with regulatory bodies (national or European)?	
Can you present the development status and manufacturing capacity for study purposes and beyond?	
Can you provide the information of the ability to provide placebo if your study blinded?	
Do you have any plan for particular imaging, laboratory assays or biobanking requisites?	
Is there any potential funding? – If applicable, briefly explain how the arm could be funded, were the molecule to be integrated into one of the platform trials?	
Are there any budget considerations?	
Are there any particular operational aspects?	

For any questions please contact the JAAM secretariat