



PROACT EU **RESPONSE**

**EMA Workshop on antivirals and mabs for
COVID 19 and influenza**

**Pandemic Preparedness Session:
Importance of pre-approved protocols**

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Protocol components



- Population
 - Intervention
 - Control
 - Outcome(s)
- Assessment (CTR)
 - Intervention
 - Manufacturing
 - Labelling
 - Investigator's brochure or SPC
 - Population
 - Risk assessment
 - Intervention vs population

Pre-approved protocol

Fully approved



- The population/diagnosis is specified such that it includes the pandemic pathogen
- E.g Approving a trial on hospitalised participants with influenza
 - Participants with H5N1 eligible
- Use viral families and not specific pathogen
 - E.g. filoviruses or corona viruses
- Use a syndromic approach, i.e. define the population from symptoms and not cause
 - E.g. Acute respiratory distress syndrome
- The broader the population, the harder the risk assessment

Pre-approved protocol

Partially approved



- Population/pathogen not known, but restrict to viral pathogens
- Known treatment
 - E.g. antivirals
- Outcomes?
 - Outcome assessment – marketing authorisation
- Platform trials, e.g. REMAP-CAP
- Conditional approval
 - Amendment required in case of pandemic

Pre-approved protocols

Other aspects



- No pathogen
- No treatment
- No outcome
- No possibility?
 - Approve "bureaucratic" parts of the protocol?
 - E.g. what to do with spurious and unused data
 - Approve sites and investigators
 - Recruitment arrangements
 - Pay fees
 - Approve data collection and data protection
 - Approve compliance with use of Biological samples

The importance of pre-approved protocols



- Speed
 - Need trials up and running as soon as possible
 - First patient within 15 days
- Resources
 - There is enough to do at the start up of a pandemic
- Quality
 - Preparation is key
- Network/agreements
 - Pre-approved protocols very helpful for networks and site agreements