Clinical Trial Task Force

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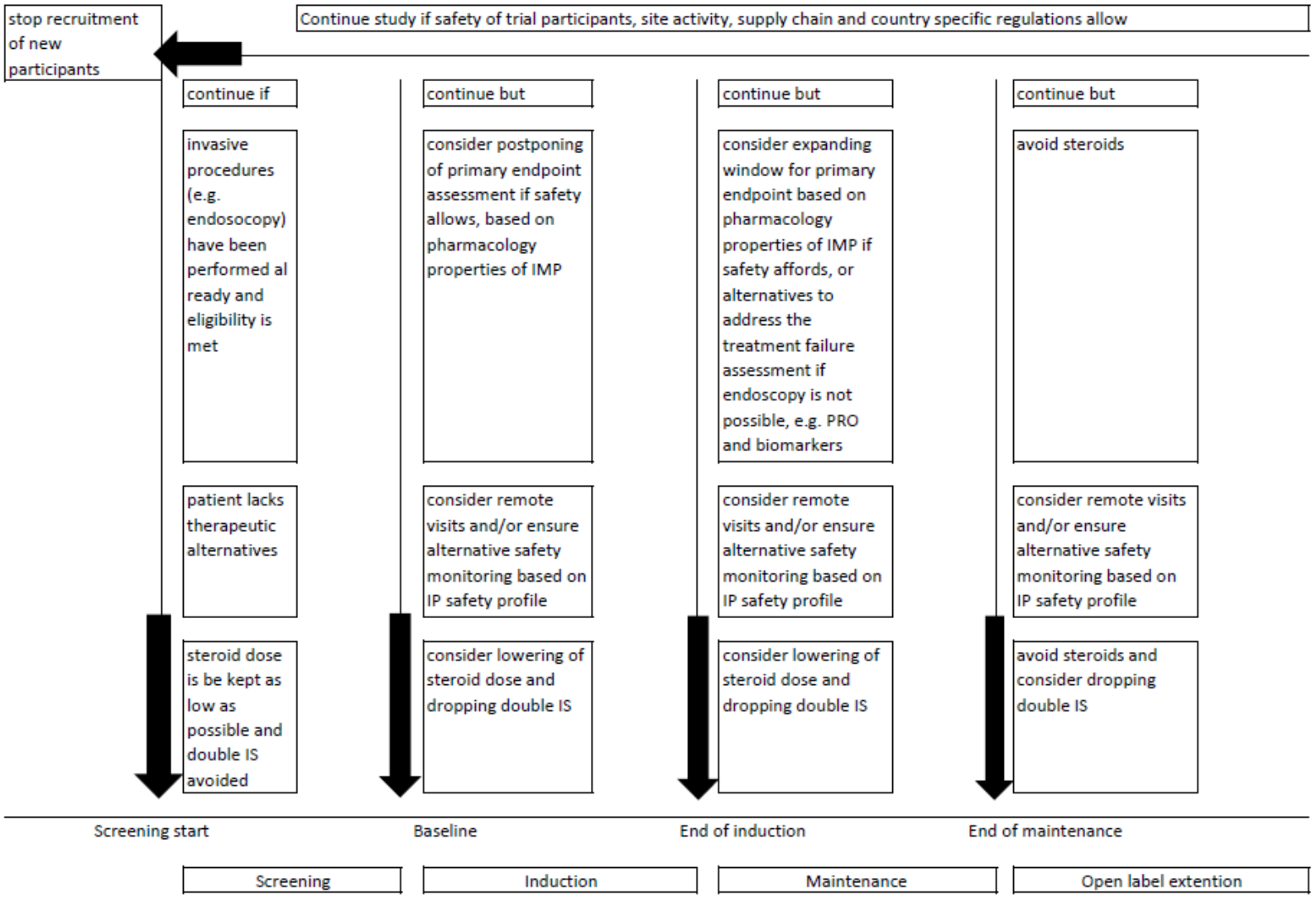
General considerations

- FDA and EMA and other regulatory authorities have issued guidance documents to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP) and minimizing risks to trial integrity during the COVID-19 pandemic
- Protocol modifications/deviations are expected and recognized due to COVID-19 illness and/or COVID-19 control measures
- Ensuring the safety of trial participants is paramount
- Sponsors need to evaluate potential impact on safety of study participants and may modify protocol accordingly. These changes to minimize risk for study participants may be implemented prior to IRB/RA approval but must be notified afterwards
- Conversion of physical visits into phone or video visits, utilization of alternative locations for assessments including local laboratory and imagine centers, home delivery and administration of investigational medicinal product (IMP), postponement or complete cancellation of visits with and without endoscopy/imaging to ensure that only strictly necessary and safe visits are performed at sites
- Track the outcome of potential SARS CoV-2 positive patients

Impact on Clinical Trials

- COVID-19 is a challenging situation leading to difficulties to comply with protocol-specified procedures, including IMP administration, adhering to protocol specified visits and diagnostic testing including outcome parameters. FDA and other regulatory authorities will require a specific documentation (CSR, submission package) of the impact of COVID-19 on individual subject data
  - Alternative process can be implemented during COVID-19 pandemic but must be clearly documented. (e.g. home administration of IMP, local lab utilization, treatment failure assessment in case endoscopy not available)
    - FDA and EMA guidance documents recommend documenting how restrictions related to COVID-19 pandemic have led to modifications in trial conduct, with documented duration of these changes and with clear documentation which trial subjects have been impacted and the extent of the impact.
  - Any changes to the conduct of the current study due to COVID-19 should be documented (e.g. missing visits, discontinuation of treatment, discontinuation of study)
- Potential risk not to achieve statistical objectives: COVID 19 situation may introduce a number of significant events that may have potential impact on evaluation and power of study objectives from missing or alternative assessments, e.g. endoscopy lacking; that warrants close monitoring and careful analysis to evaluate the risk on integrity and trial outcome.



Screen for covid symptoms and potential patient exposures before each visit
Discontinue study or pause study drug in patientswith confirmed SARS CoV-2 infection dependent upon severity of symptoms