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Submission of comments on

Guidance on the conduct of clinical trials during public health emergencies EMA/44884/2026

When completed, this form should be sent to the European Medicines Agency electronically, in Excel format (not PDF), to the following address:
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All the cells with an asterisk (*) should be filled in prior to completing the columns "Comment and rationale" and/or "Proposed changes / recommendation".
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Name of organisation or individual*	Line from* (line Nr or 0 for general comment)	Line to* (line Nr or 0 for general comment)	Section number	Comment and rationale (to go to next line within the same cell use Alt + Enter)	Proposed changes / recommendation (if applicable - to be used if you want to propose specific text changes)
LUNGevity Foundation	58	62	1	While we agree that "small, isolated clinical trials" may not provide the same level of evidence as a larger clinical trial in all circumstances, we caution the recommendation to deprioritize these smaller trials in a PHE. Patients in small communities may not have access to large clinical trials offered at large medical institutions, and therefore recommending that smaller trials not be prioritized may significantly limit patient access to clinical trials. Additionally, "small, isolated clinical trials" is contrasted in the section by "well-designed clinical trials". These are not dichotomous terms, as a small trial by patient number (e.g., for a rare disease) can be well-designed. We recommend against using language related to size of the trial as an indicator of design robustness.	A key lesson learnt from the COVID19 pandemic is that inadequately designed or controlled trials or compassionate use programmes…
LUNGevity Foundation	66	69	1	We are concerned by the language that the priority for the initiation of new clinical trials should be those studying the medical condition associated with the PHE. As noted in line 54, clinical trial conduct should take a risk proportionate approach. The PHE may not be as serious or life-threatening on an individual basis as other serious diseases or conditions, and therefore the implication that these trials for serious conditions should be deprioritized during a PHE is potentially extremely detrimental to patients with life-threatening illnesses. We would encourage the continued use of a risk-based approach for prioritization of clinical trials, rather than automatic prioritization of those linked to the PHE.	
LUNGevity Foundation	100	104	2	As noted above, we are concerned with language supporting placing the assessment of clinical trials on hold based on urgency, particularly as it is unclear how "urgency" should be interpreted. While a clinical trial may not be related to the condition associated with the PHE, it may, and should, still be considered "urgent" when pertinent to the treatment of patients with non-PHE-related life-threatening diseases. Line 104 states that all trials should be evaluated based on their relevance to the PHE. We are concerned that clinical trials for life-threatening illnesses will be put on hold or stopped, which should not be the case under a truly risk-based approach. Line 114 addresses these types of trials, but they are not alluded to in either lines 100-104 or lines 66-69.	
LUNGevity Foundation	147	209	3	Section 3 outlines the handling of substantial modifications (SMs) to clinical trials during a PHE. In the US, the National Cancer Institute (NCI), in their memorandum on clinical trials during COVID-19, distinguished between major protocol deviations and minor protocol deviations. While minor deviations still needed to be recorded and reported, they need not require the same level of documentation as major deviations. Minor deviations included changing in-person study visits to phone/videoconferencing, delayed laboratory and/or imaging assessments, treatment delays, and changes to biospecimen collection. However, some such minor deviations, such as replacing physical visits with remote visits, are considered by the guidance and in the CTA Q&A referenced therein as SMs, despite posing considerably less risk than other changes. For example, when done correctly, implementing remote consent (line 191) is much less likely to "jeopardize trial participant safety, data integrity, and reliability" than a temporary halt of a clinical trial. We implore the reconsideration of how certain procedures are categorized as either substantial or non-substantial modifications, particularly in the context of a disruptive PHE that would make such modifications necessary.	
LUNGevity Foundation	266	304	4	We support the use of remote informed consent to ease patient burden, regardless of a PHE. We are concerned by the level of evidence required for documentation of consent outlined in this section to confirm consent. For reference, during COVID-19, the US Food and Drug Administration (FDA) instructed that (1) information may be presented in writing, through verbal dialog, or a combination of approaches; (2) consent may be written or oral; (3) documentation of consent must be signed and dated but does not have to be on paper or performed in person and/or at the study site; and (4) there must be a system for archiving consent documentation. We urge alignment of expectations for remote informed consent across regulatory agencies to reduce unnecessary burden imposed on patients.	
LUNGevity Foundation	324	326	4	We support the guidance to waive the collection of certain safety data if it will not impact the interpretability of results or patient safety. We recommend decreasing the collection of low-grade adverse events and other data points to minimize effects of minor protocol deviations on protocol conduct, rather than collecting every recorded event irrespective of importance and relationship to the study endpoints.	
LUNGevity Foundation	347	403	4	As requiring patients to pick up short-duration study drug prescriptions in person can pose a barrier to trial enrollment and retention, we support home delivery of investigational products. The guidance should ensure that sponsors and investigators keep records of when, how much, and to whom study therapy is shipped. Additionally, investigators must ensure that study participants understand and comply with protocols for administration and disposal of study therapy and have appropriate resources for compliance.	