RECOVER-TLC intervention information request form

BOLD: Concept categories to be grouped together as questions on a single page (Individual data request questions are below)
ITALICS: Actual input expected from the request.

Submitter information (page 1 of 5)

*Name**
*Affiliation (i.e. patient, caregiver, company, university, etc.)**
*Email address**
Phone number
*Name of intervention**
Intervention owner/sponsor, if any

Therapeutic general information (page 2 of 5)

1) Type of therapeutic intervention *(drug, device, other)*
2) Class
    a. If *drug* was selected in (1) [*biologic, small molecule, other (with text box*)]
    b. If *device* was selected in (1) [*class I, class II, class III, PMA, HDE, 510K, other (with text box*)]
    c. If *other* was selected in (1) (*text box*)
3) Stage of overall development: *(approved for another indication, phase 2/3, phase 1, preclinical)*
   *(**Note:** priority will be given to assets that are approved or ready for advanced clinical development)*
4) If approved, current indication(s) *(acute COVID, other indication [text box])*
5) Symptoms/syndromes intervention aims to target (*text box*)
6) Mechanism of Action [*text box – 250 words*]
7) Scientific Rationale (proposed mechanism to improve symptoms in Long COVID) [*text box – 250 words*]
8) Safety data if *drug* was selected in (1)
    a. Is safety data available? [yes (*text box*) or no]
    b. Is signal specificity known? [yes (*text box*) or no]
    c. If there is a drug label, please provide link (*text box*)
9) Pediatric Data
    a. Pediatric approval *(yes or no)*
        i. *If no to (9a):* prior pediatric testing data available? *[yes (text box) or no]*
10) Pregnant and lactating women data
    a. Approval in this population *(yes or no)*
        i. *If no to (10a):* prior testing data available in pregnant and lactating women? *[yes (text box) or no]*
11) Summary of human PK/PD data if *drug* was selected in (1):
    a. Route of administration (*text box*)

b. Tissue distribution (*text box*)
c. CNS penetration (*yes, no, unknown*)
d. Plasma protein binding, including metric (*text box*)
e. Clearance mechanism (*text box*)
f. Solubility (*text box*)

Clinical data, if any (page 3 of 5)

1) Clinical data for a Long COVID-19 indication
    a. Clinical trial/study info: i.e. case, single arm, RCT (*text box*)
    b. Study target accrual (*text box*)
    c. Study status (*completed or ongoing*)
2) Clinical data for an acute COVID-19 indication (if not already approved for COVID-19)
    a. Clinical trial/study info: i.e. case, single arm, RCT (*text box*)
    b. Study target accrual (*text box*)
    c. Study status (*completed or ongoing*)
3) Clinical data for other indication (if not already approved for other indication)
    d. Clinical trial/study info: i.e. case, single arm, RCT (*text box*)
    e. Study target accrual (*text box*)
    f. Study status (*completed or ongoing*)

Preclinical Data Related to Drug, Device and Other Interventions (only complete if not yet in clinical trials) (page 4 of 5)

2) Efficacy in animal model data:
    a. Animal models tested (*text box*)
    b. Route of administration (*text box*)
    c. Dose administered (*text box*)
    d. Summary of efficacy data (*text box*)
    e. Adverse events (*text box*)

Drug, Device, or Other Intervention availability/scalability (page 5 of 5)

1) Is the current intervention supply sufficient for a clinical trial? (*yes or no*)
    a. If *yes* to (1), enough supply for *2500 active courses*? (*yes or no*)
    b. Do you have a corresponding placebo for the intervention? (*yes or no*)
        i. If *yes* to (1b), is there enough supply for *2500 placebo courses*? (*yes or no*)
2) Is the current intervention supply sufficient to deploy to the general population if trial generates positive results and EUA is issued (>100,000 courses available)? (*yes or no*)
3) Can the intervention be manufactured quickly to scale up for broad use? (*yes or no*)
    a. What are the timelines? (*text box*)
    b. Do you have manufacturing capabilities already? (*text box*)

URL links to critical data for agent consideration: (page 5 of 5) (*Up to 6 links*)