Coronavirus Treatment Acceleration Program (CTAP)

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FDA has created a special emergency program for possible therapies, the Coronavirus Treatment Acceleration Program (CTAP). It uses every available method to move new treatments to patients as quickly as possible, while at the same time finding out whether they are helpful or harmful. We continue to support clinical trials that are testing new treatments for COVID so that we gain valuable knowledge about their safety and effectiveness.

Snapshot for Developing Therapeutics

Given the urgent nature of the pandemic and the number of companies and researchers developing COVID-19 related therapies, the following numbers may change frequently. Our current snapshot is:

- 10 therapeutic agents in active trials
- Another 15 therapeutic agents in planning stages

Please send requests for product development for proposed COVID-19 uses and drug development to: COVID19-productdevelopment@fda.hhs.gov (mailto:covid19-productdevelopment@fda.hhs.gov). Thank you

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Examples of CTAP in Action

- Immediately upon receipt, triaged requests from developers and scientists seeking to develop or evaluate new drug and biologic therapies, getting the right FDA staff in touch with them and the work to get studies going fast. With a first wave of requests behind us, FDA will generally respond within a day.
- Provided ultra-rapid, interactive input on most development plans. Interactions are generally prioritized based on a product's scientific merits, stage of development, and identification as a possible priority product in consensus USG documents.
- Provided ultra-rapid protocol review – within 24 hours of submission, in many cases.
- Completed review of single patient expanded access requests around-the-clock – and generally within 3 hours.
- Worked closely with applicants and other regulatory agencies to expedite quality assessments for products to treat COVID-19 patients and to transfer manufacturing to alternative or new sites to avoid supply disruption.

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Support for CTAP

- Redeployed medical and regulatory staff to review teams dedicated to COVID-19 therapies.
- Involved senior management in review of submissions.

- Redeployed medical, operations, and policy staff to support the overall effort.
- Streamlined processes and operations for developers and scientists to send us inquiries and requests.
- Provided resources to healthcare providers and researchers to help them submit emergency requests to use investigational products for patients with COVID-19 infections.

We will continue to enhance and expand CTAP. To the extent permitted by confidentiality laws, we'll post summary statistics, keep the public updated, and link to public information about ongoing clinical trials and to summaries of drugs in clinical and preclinical development.

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