힘내라 대한민국 Ministry of Food and Drug Safety	**보 도 자 료**	배 포	2020. 5. 28.(목)
		담 당 과	식품의약품안전평가원 종양약품과 (☎043-719-3051)
		과 장	김영림 (☎043-719-3051)
		사 무 관	최경숙 (☎043-719-3053)

Easier entry into clinical stage for COVID-19 medicine

Ministry revises guidelines on development of COVID-19 medicine to minimize trial and error in clinical trials

☐ The Ministry of Food and Drug Safety (Minister Lee Eui-kyung) published "Things to consider when **developing COVID-19 medicine"** (Guidelines) in April to **accelerate** entry into **the clinical stage** and reduce trial and error.

○ These guidelines deal with the submission data and requirements to be considered when designing clinical trials, including the methods and examples of efficacy tests based on the action mechanism of antiviral and anti-inflammatory drugs, the types of necessary toxicity test data, subjects of trials and assessment items.

○ The guidelines were **revised** to **reflect** additionally collected **domestic and foreign clinical trial information** and **guidelines** of **foreign regulators**.

- Added to the revision include things to be considered in clinical trials for checking prevention and treatment effects, specification of clinical trials evaluation variables, recommendation of sub-analysis for age and other items that can affect the results of statistical analysis, analysis of safety and inefficiency by an "Independent Data Monitoring Committee."

- The disease severity classification criteria of the WHO and the US FDA were also attached to the appendix for developers planning multinational clinical trials in the midst of the difficulties in clinical trials caused by a decrease in the number of patients.

☐ The Ministry of Food and Drug Safety has **designated and operated** a "**consultation window dedicated to COVID-19"** and an "**exclusive manager"** for highly potential items as part of the "**Go·Fast Program"** aimed at rapid commercialization of COVID-19 medicines and vaccines.

○ So far, this program has offered **customized consultation** to **24 companies** to help

them **enter the clinical trial**.

* The average number of days needed to review and approve 12 cases of clinical trials for COVID-19 medicine: within 7 days

○ The ministry provides information about **clinical trials through frequently asked questions and answers (Q&A)** of its website.

- Guidelines and Q&A can be found on the MFDS website (www.mfds.go.kr) > banner > GO·Fast program > technical support.

□ The Ministry of Food and Drug Safety will continue to cooperate with related government agencies, industry, academia, and medical circles and do its best for the development of safe and effective medicines and vaccines people have been waiting for.