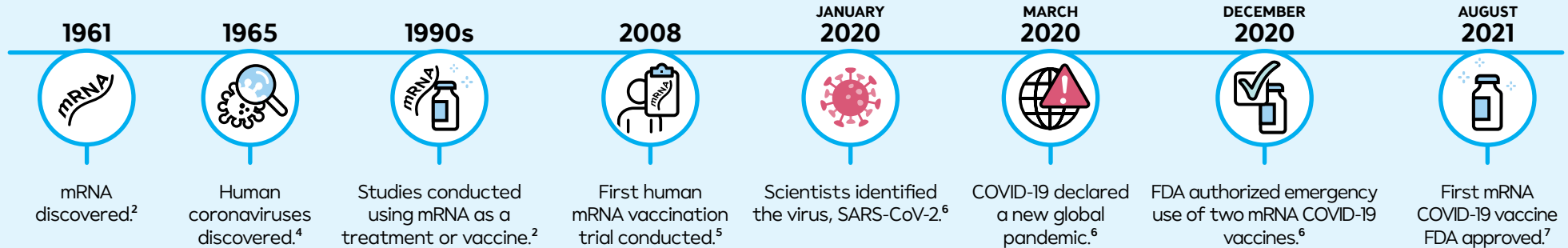


HISTORY OF mRNA COVID-19 VACCINES



mRNA is a molecule that carries instructions for cells to make proteins.¹

Research on coronaviruses and mRNA **started long before the COVID-19 pandemic.**^{2,3}



mRNA COVID-19 Vaccine Development Process: Approximately 12 months⁸



INITIAL DEVELOPMENT

Using knowledge gained from previous mRNA research, scientists developed potential vaccines for COVID-19.⁸ Scientists must submit an application for an Investigational New Drug to the FDA. This includes information on⁹:

- Results from lab research and animal testing
- How the vaccine is made
- Quality of the vaccine

Human trials cannot start without FDA's authorization.⁹



HUMAN TRIALS

- Phase 1:** Evaluates safety and immune response within healthy people¹⁰
- Phase 2:** Includes people of different states of health and backgrounds to continue safety and immune response evaluation¹⁰
- Phase 3:** Evaluates efficacy and safety in people who received the vaccine compared to those in a control group who received a placebo¹⁰



FDA EMERGENCY USE AUTHORIZATION

The FDA determined that the known and potential benefits outweighed the known and potential risks of the vaccines, and granted Emergency Use Authorization (EUA).^{10,11}



VACCINE MANUFACTURING



FACT:

mRNA COVID-19 vaccines were developed using mRNA research dating back to the 1960s.²

COVID-19 vaccines were developed quickly for many reasons including⁸:

- Improved regulatory review process
- Increased funding
- New vaccine technology
- Shortened production times
- Expanded manufacturing capabilities

Overlapping Initial Development and Human Trials helped accelerate the timeline. During vaccine development, all FDA required steps were taken in the clinical development process.^{8,11}



To learn more, visit:

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