

## ATTACHMENT A — DEFERRAL REQUEST

Product Name	COVID-19 Vaccine (BNT162, PF-07302048)
IND number	019736
Applicant	BioNTech
Proposed Initial Indication	Active immunization against COVID-19 in individuals $\geq 16$ years of age
Future Supplemental Indications	Active immunization against COVID-19 in children and adolescents 12 through 15 years of age; Active immunization against COVID-19 in children and infants $< 12$ years of age.
1. Pediatric age groups for whom deferrals are requested	Adolescents, children, and infants 15 years of age and younger
2. Reason for requesting deferral of pediatric studies (address each age group separately and for each group choose all that apply):	<p>A deferral of the evaluation of the COVID-19 vaccine in individuals <math>\leq 15</math> years of age is requested based on the following Criteria for Deferral (Section 505B(a)(4)(A)(i)(I) of the Act): “Pediatric studies should be delayed until additional safety or effectiveness data have been collected” and “The drug or biological product will be ready for approval for use in adults before pediatric studies are complete.”</p> <p>Adequate evidence of safety and efficacy has been established in the pivotal study C4591001 in individuals <math>\geq 16</math> years of age to allow Emergency Use Authorization in that age group. Study C4591001 includes subjects 12 through 17 years of age. It was appropriate to defer studies in children 6 months to <math>&lt; 12</math> years of age until adequate safety and immunogenicity information was available in 12- through 15-year-old children and adolescents. It would then be appropriate to defer further age-de-escalation to <math>&lt; 6</math> months until adequate safety data is available in 6 month through 11-year-old children.</p>

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| 3. Pediatric age group(s) not included in the deferral request                                    | Children and adolescents 16 through 17 years of age                                                                                                                                                                                                                                 |
| 4. Reason for not including the pediatric age group(s) listed in number 3 in the deferral request | Study C4591001 includes subjects 16 through 17 years of age                                                                                                                                                                                                                         |
| 5. Has a pediatric plan been submitted to the Agency.                                             | Yes                                                                                                                                                                                                                                                                                 |
| 6. Suggested deferred date for initiation and submission of studies                               | The initiation date for Study C4591007, a safety and effectiveness study in children <12 years of age, was 24 March 2021. The estimated initiation date for Study C4591023, a dose-finding safety and effectiveness study in infants less than 6 months of age, is 31 January 2022. |

## Document Approval Record

**Document Name:**

Deferral Request for PF-07302048 (COVID-19 Vaccine) July 2021 - A  
greed Pediatric Study Plan

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**Signed By:****Date(GMT)****Signing Capacity**

Harkins Tull, Elisa

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Regulatory Affairs Approval