

A fresh start for advanced therapy clinical trials



2020 was a volatile year for cell and gene therapy R&D, but important progress persevered. Here are some of the numbers that mattered most—and a few that point to a coming rebound.



A continued focus on early-phase research...

1,220 Advanced therapy clinical trials world-wide in 2020¹

1,068 Phase I/II trials (88%)



Clinical disruption due to COVID-19...

55% of CGT companies reported:



pausing clinical site activation for planned trials²



pausing patient recruitment at existing clinical sites²



missing patient follow-up assessments²

45%

anticipate a 3-6 month delay in development programs²



And regulatory challenges and delays...

20% of traditional drug regulatory review focused on product and CMC (Chemistry, Manufacturing, and Controls) issues³

80% of a cell therapy regulatory review focused on product and CMC issues³

75% of late-stage advanced therapy regulatory reviews delayed in 2020 due to product and CMC issues⁴



All while preparing for a year full of promise in 2021.

\$19.9B Total 2020 advanced therapy global financing—on pace to be a record-breaking year⁵

59K+ Total potential patient enrollment in advanced therapy clinical trials⁶

Here at Vineti, we're proud to be part of a resilient advanced therapy sector that has kept progressing amid the challenges of COVID-19. And we're keeping pace, with proven operational solutions and expertise that accelerate advanced therapy clinical trials.

Want to learn more? See the [FDA's 2020 guidance](#) for CMC in gene therapy Investigational New Drug Applications. And please [connect with us](#) with questions about your advanced therapy clinical trials.

1. Alliance for Regenerative Medicine, 2021; 2. McKinsey & Company, 2020; 3. U.S Food and Drug Administration, 2018; 4. Proprietary Vineti research, 2020; 5. Alliance for Regenerative Medicine, 2021; 6. Alliance for Regenerative Medicine, 2019.

LET'S CONNECT

www.vineti.com • email: sales@vineti.com • call: (415) 704-8730

©2021 Vineti, Inc. • 633 Howard St. • San Francisco, CA • 94105