
By Omer Baker, BS Candidate; Nancy Pire-Smerkanich, DRSc

Objective
To investigate the effectiveness of current federal guidances towards accelerating availability and development of COVID-19 testings, treatments, and vaccines

Background
- **February 4** | In-Effect Emergency Use Authorization Guidance (EUA)
- **March 31** | Coronavirus Treatment Acceleration Program (CTAP) Established
- **April 17** | Accelerating COVID-19 Therapeutics Interventions and Vaccines (ACTIV) Launched
- **May 11** | Updates to EUA Guidance
- **July 8** | COVID-19 Prevention Trials Network (COVPN) Launched
- **July 12** | 9% of ~41 million COVID-19 viral tests in the United States (US) were positive
- **Today** | US, which composes of 4% of the world's population, has ~27% of global COVID-19 cases

Methodology
**Part 1** | General Overview of Assessing FDA Authorizations and Clinical Trials
- FDA Authorizations and Clinical Trials
  - Diagnostic Testings: Accuracy Parameters
  - Treatments: Recovery Rate
  - Vaccinations: Immune Response

**Part 2** | Examination of FDA Documents for Diagnostic Testing
- Comprehensive review of FDA guidance before and after COVID-19
- Compile List of Authorizations and Recalls/Withdrawals for COVID-19 developments
- Evaluate approval rates for applications between diagnostic testing, treatments, and vaccinations

Findings
**Emergency Use Authorizations**
- **158** In Vitro Diagnostic Products & High Complexity Molecular-Based Laboratory Developed Tests
- **33** Serology Antibody Tests
- **2** Antigen Tests

Average sensitivity of IgG and IgM antibodies in serology antibody tests (n=7) was >92% when tested 14-25 days after symptom onset

**Coronavirus Treatment Acceleration Program: Approval Rate**
- Denied proposals: 22.9%
- Trials reviewed and approved by FDA: 24%
- Drug development in planning stages: 53.1%
- n = 950 proposals

Conclusions
While the extreme circumstances have challenged the regulatory systems in the US, current federal guidances have failed to produce reliable diagnostic tools as seen by the inconstant testing accuracies and the high CTAP approval rate of 77.1%. Without a reliable system on all fronts to accurately and promptly deliver diagnoses, the COVID-19 pandemic has and will continue to escalate. To support treatment accelerations, clinical researchers and government agencies should work in conjunction to practice standardization and public transparency of clinical data.

Contact Information
Omer Baker, BS Candidate
omerbake@usc.edu

Part 1 | General Overview of Assessing FDA Authorizations and Clinical Trials
Part 2 | Examination of FDA Documents for Diagnostic Testing
Omer Baker, BS ’22 is a rising junior at USC studying Human Biology and Global Health on a Pre-Medicine track. With the goal of protecting the world’s most vulnerable children, he has been involved with UNICEF since 2014 through positions on the UNICEF USA National Council and as the U.S. Ambassador to the UNICEF Global Advisory Board. In his role at UNICEF, he has worked alongside executive staff on fundraising and critical programming initiatives including GenUnlimited and the Convention on the Rights of the Child. Inspired by the organization’s lifesaving work, he hopes to further his ambitions through a career as a physician and researcher. In his community, he has also advanced his clinical experience through volunteering with two local hospitals in Los Angeles. He has also gained research experience over the past three years through various investigator-initiated clinical studies primarily rooted in the field of plastic surgery — with a main focus on grant proposals, IRB applications, and publications for leading medical aesthetic drug corporations such as Galderma and Allergan, he has learned the value of modern innovation in medicine and pharmaceuticals. Most recently, he was a secondary investigator on a retrospective clinical review of the safety and efficacy of poly-L-lactic acid for gluteal augmentation in patients. He is excited to further his research background with a focus on expedited regulatory mechanisms in the context of COVID-19, focusing on the limitations of the federal regulations in the time of an unprecedented global health crisis. In his free time, you can find Omer exploring Los Angeles with friends, enjoying a day at the beach, and traveling! omerbake@usc.edu