These expedited mechanisms have been implemented to approve diagnostic testing and treatments, without a reliable system to accurately and promptly deliver results. Preliminary study results indicate that current federal guidance has failed to produce reliable diagnostic tools and treatments:

- Inconsistent testing accuracies and high relative percentage of EUA revocations,
- Extremely low denial rate for proposals through CTAP, given the low yield of treatments authorized.

The lack of uniform testing and qualification strategy has been a major setback in terms of holistic pandemic response, and consequently called into question the reliability of subsequent data collection.

METHODOLOGY

1. General Overview of Assessing FDA Authorizations and Clinical Data

   Diagnostic Testings:
   - Accuracy Parameters (sensitivity, specificity, percentages of false positive/negative results)

   Treatments:
   - Treatment Types: antivirals, cell & gene therapies, immunomodulators, neutralizing antibodies

2. Examination of FDA Documents for Diagnostic Testings and Treatments

   - Comprehensive review of FDA guidelines before and after COVID-19
   - Assess and compare successful approvals versus unsuccessful approvals

RESULTS

Diagnostic Testings

- EUA Revocations: 31.9%
- EUA Standing Approvals: 68.1%

Figure 1: Breakdown of EUA Outcomes for Diagnostic Testings (n = 333)

- Other treatments
- Antivirals: 10.3%
- Cell & Gene Therapies: 10.3%
- Immunomodulators: 33.3%
- Neutralizing Antibodies: 12.8%

- Combination: 7.7%

Figure 2: CTAP Treatments Types

Figure 3: Breakdown of CTAP Outcomes (n = 960)

Eight COVID-19 treatments are currently authorized for emergency use: five neutralizing antibodies, two immunomodulators, and one antiviral. One treatment is currently FDA approved for COVID-19.

CONCLUSIONS

- These expedited mechanisms have been implemented to approve diagnostic testing and treatments, without a reliable system to accurately and promptly deliver results.

- Preliminary study results indicate that current federal guidance has failed to produce reliable diagnostic tools and treatments:
  - Inconsistent testing accuracies and high relative percentage of EUA revocations,
  - Extremely low denial rate for proposals through CTAP, given the low yield of treatments authorized.

- The lack of uniform testing and qualification strategy has been a major setback in terms of holistic pandemic response, and consequently called into question the reliability of subsequent data collection.