

# 48-Hour Turnaround Time: Achieving Faster eCTD Submissions with eCTD Submit



## AT A GLANCE

A major cell therapy organization and their client had 5 FDA interactions within a very short time frame—requiring the submission of multiple response documents all at once.

The eCTD Submit team turned around publishing in just two days. This was accomplished through their deep regulatory expertise in eCTD submission, effective communication and adaptability, and their highly efficient submission software.

## CHALLENGES

The large submission was scheduled just a few days following the large influx of required responses to the FDA. Publishers usually needed weeks to prepare successful submissions for this size of workload, so naturally the client was nervous about meeting such an abrupt deadline.

## OUR APPROACH

eCTD Submit reassured the client the scope of the project was well within capabilities. In fact, the eCTD Submit team was able to successfully return all FDA response documents in 2 days. Afterwards, an astonished client expressed how eCTD's overall publishing time was half of what they'd experienced with other publishers.

## THREE KEY POINTS

1

### Two-Day Turnaround

eCTD Submit's expertise and flexibility means rapid turnarounds for your submissions.

2

### Complete Review of Documentation

Our eCTD Navigator tool enables complete review of all your relevant documents while remaining cost-efficient.

3

### Error-Free QC

eCTD Submit brings experience backed by diligence, meaning your documents come back right the first time.



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## SOLUTIONS

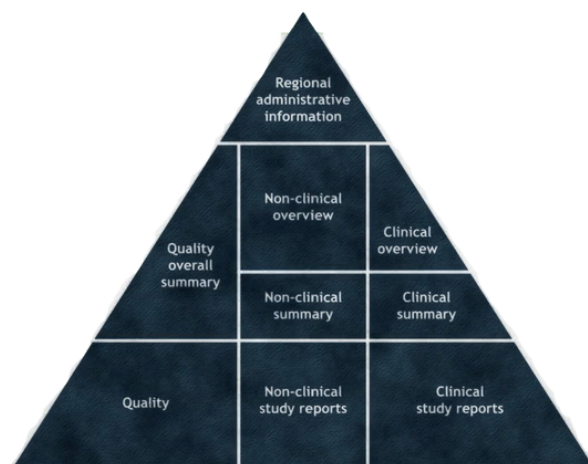
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In this case, the client's smooth experience working with us—our expertise in eCTD submission, the quality of our work, and an amazingly quick turnaround time—solidified an ongoing, positive collaborative relationship.

## WHO WE ARE

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At eCTD Submit, our deep experience in FDA publishing avoids the delays and hang-ups that all too often occur with other publishers who struggle to meet short timeframes and sudden deadlines. We've managed thousands of successful applications; When you work with eCTD Submit, you experience direct access to trusted regulatory experts in eCTD who are able to quickly understand your unique needs.



With user-friendly templates, compliant submissions are simple for even first-time users. And you can easily transfer your existing applications into our Navigator system without losing data in transition. With our intuitive web-based eCTD Navigator, you'll achieve diligent and complete QC review of all your relevant documents while remaining comfortably within budget.

Our clients continue to return to eCTD Submit, even as they move between organizations, a testament to the high levels of trust and satisfaction with our services.

## CONTACT US TODAY

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