New Expanded Access eRequest System Enables Online Submission of Non-emergency Single-Patient Requests

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Abstract

FDA's Expanded Access (EA) program permits the use of an investigational drug to treat patients with a serious or immediately life-threatening disease who lack therapeutic alternatives. The EA regulations were updated in 2009, and since then, FDA has continued to clarify and promote the program while streamlining and simplifying its use for patients and providers.

In September 2020, the eRequest mobile site was launched on the Reagan-Udall Foundation for the FDA's (RUF) website. eRequest was designed and developed in conjunction with FDA staff to ensure that regulatory and technical requirements were met to create and submit an online non-emergency, single-patient expanded access request with all necessary documentation (see Figure 1).

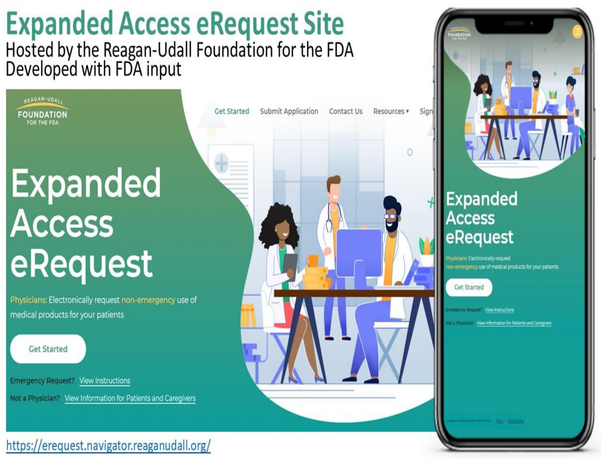

Figure 1. eRequest Landing Page for Laptop or Mobile Device

Introduction

The FDA Expanded Access eRequest Working Group designed and implemented a groundbreaking Expanded Access eRequest web application (app; https://erequest.navigator.reaganudall.org/) to help physicians determine whether EA is appropriate for their patients and walk them through the process of completing Form FDA 3926 (for an Individual Patient IND) and submitting it to FDA. Development began in early 2019. Despite transitioning to full-time remote work and multiple deployments by key staff in the Public Health Service, progress continued steadily and eRequest launched on September 23, 2020 on the RUF website. Prior to eRequest, there was no platform to submit online EA requests, which was a common stakeholder request. eRequest is the latest of a series of steps that show FDA's commitment to patients who need access to investigational treatments.

Materials and Methods

- In 2019, Expanded Access eRequest Working Group began holding weekly calls with external software developers and RUF on refining the goals of the site and building toward its launch.
- FDA's Expanded Access Coordinating Committee (EACC) members were key advisors in monthly meetings and ad hoc public outreach in ensuring all key components were captured.
- Multiple rounds of testing were conducted (February, May, and September 2020) leading toward improvements in the site's intuitive flow and functionality.
- The release of eRequest was communicated publicly, including in a blog post by Principal Deputy Commissioner, Amy Abernethy.

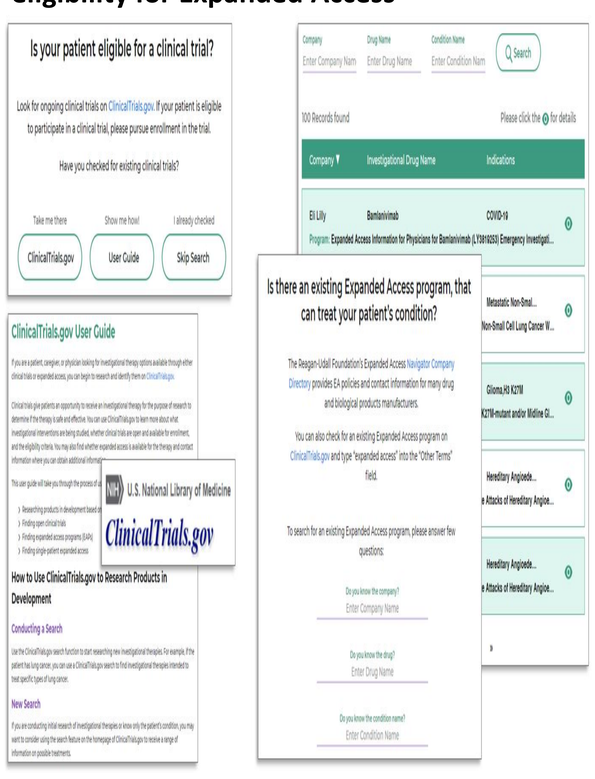

Figure 2. eRequest Helps Physicians Determine whether Expanded Access is the Correct Option for their Patient's Treatment Needs

Results and Discussion

eRequest assists physicians with screen-by-screen navigation through the EA process – from determining whether EA is appropriate for their patient to submitting the request electronically to FDA (see Figure 2). Physicians can identify potential investigational therapies; access sponsor information; complete, sign, and submit Form FDA 3926 (see Figure 3); upload supporting documentation; and review additional resources all in a single online location. The site is compatible with multiple devices, including laptops and mobile phones, so physicians can explore EA in real time with their patient and submit the request electronically when completed (see Figure 4). Through the end of March in FY21, FDA has received 376 single patient expanded access requests. As of April 2021, 30 of them were submitted through eRequest, and FDA expects the site's uptake to continue to grow.

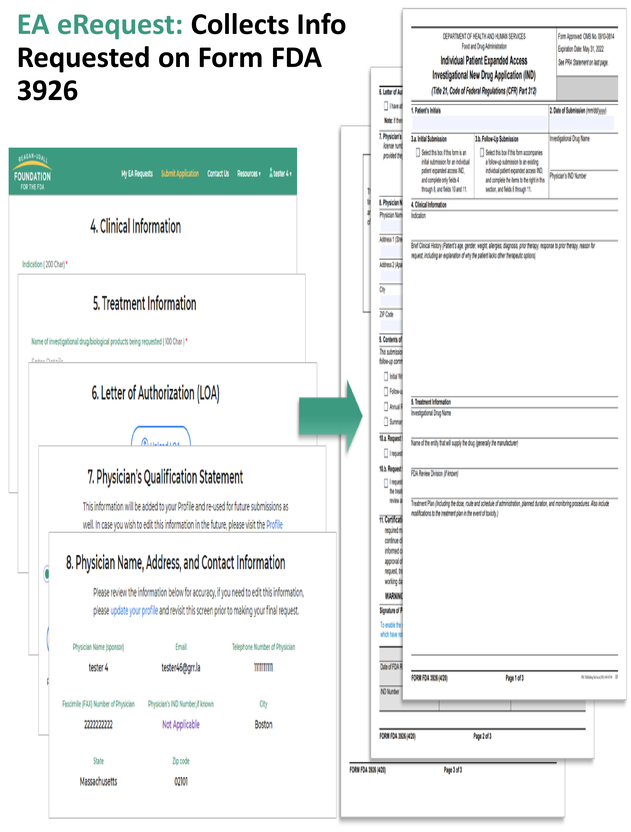

Figure 3. Data Entered through eRequest is Used by the Site to Generate Form FDA 3926 *Individual Patient Expanded Access Investigational New Drug Application (IND)*

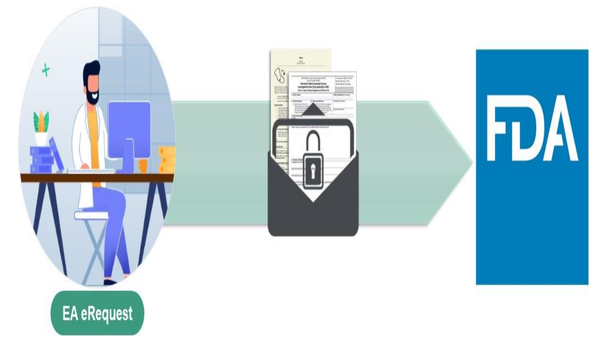

Figure 4. Once the Submission Package is Complete (with necessary attachments) and Electronically Signed, it is Submitted to FDA for Review

Conclusion

Patients seeking access to medical products under FDA's EA program are among our most vulnerable, and time is critical. Patient providers' focus should be on the clinical aspects of care.

eRequest demonstrates FDA's ongoing commitment to EA stakeholders, especially the patients and their providers. We strive to continue making the process easier for all involved while continuing to facilitate access to these important investigational medical products for treatment. FDA hopes that eRequest grows to become a popular way to submit EA requests

FDA will continue to work with the RUF on expansions and refinements to eRequest, possibly including follow-up submissions, emergency requests (in certain situations), and a physician dashboard for providers to more easily track and manage their submissions.

Acknowledgments: Thank you to the patient community, the Reagan-Udall Foundation and the Expanded Access Coordinating Committee. Thank you to the Frontline hospitals, healthcare workers and all essential workers.