

Regulatory Team Increasing Efficiency and Reducing Footprint in the Office

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1. Background

The COVID-19 pandemic affected almost every aspect of personal and professional life, changing how our whole office functioned. Like most institutions, the early pandemic forced remote work for many of our staff. This shift resulted in major changes to our internal workflows — many involving how we shared and documented information. We had already made a huge push toward electronic regulatory binders in 2019, but before 2020 were still maintaining physical binders for each study with many paper and wet-ink documents. This practice was causing paper waste, as many documents were unnecessarily printed and filed in a physical binder (in duplicate with the electronic binder). This was resulting in space inefficiencies, as our office was struggling to find space to house large investigative site files. And finally, at a large and sprawling institution like University of Cincinnati (UC), this was causing inefficiency in trying to locate investigators and obtain wet-ink signatures from across the campus.

2. Goals

With pandemic-driven remote work, it quickly became necessary to achieve 100 percent electronic regulatory binders, with all documents and signatures filed electronically, and completely eliminate the need for paper documents, physical binders, and wet-ink signatures.

3. Solutions and Methods

Working in collaboration with our electronic regulatory service, Complion, we adapted many standard operating procedures (SOP) and workflows to revolve around our electronic binder. This shift included electronic conflict of interest forms, electronic monitoring logs, and fully electronic delegation logs. Additionally, we shifted our practice such that we use electronic signatures on all documents, and electronic attestation of training; fully eliminating the need for paper and wet-ink signatures.

4. Outcomes

From 2019 to 2020 we saw a 55 percent increase in the number of documents filed electronically (Figure 1 – 2019: 4,716 vs. 2020: 10,417) From 2019 to 2020 we saw a 50 percent increase in the number of electronic signatures obtained through Complion (Figure 2 – 2019: 3,866 vs. 2020: 7,743) We have also been able to see a significant decrease in the average number of boxes of paper ordered by our office per month, decreasing 40 percent from 2019 to 2020 (Figure 3 – 2019: 4 vs. 2020: 2.4).

5. Lessons Learned

We continue to educate our collaborating sponsors and clinical research organizations on our electronic system, the electronic signatures and training documentation, how they can use Complion to document visits, and eliminating the need for a physical trial master file. We hope in the future to eliminate other areas where paper and physical documentation can be eliminated across the office. A paperless future will require creative implementation of our electronic systems and modified workflows and SOPs. While

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the pandemic has brought devastation in many areas of life, there have also been creative and innovative achievements that have occurred, especially in the workplace. We see our achievements as an increase in productivity and efficiency, as well as an important step toward sustainability and a small step to reducing the footprint we leave.

Figure 1

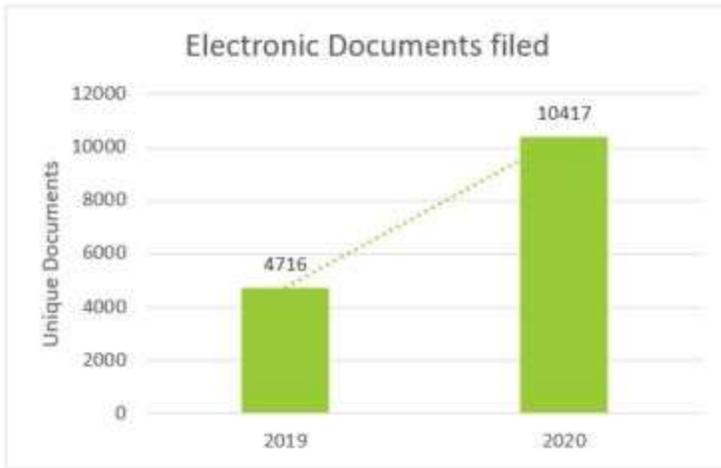


Figure 2

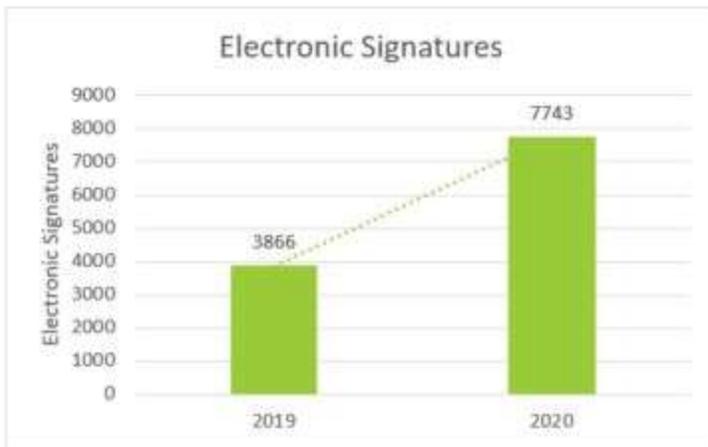


Figure 3

