

REGULATORY TIPS AND UPDATES— DID YOU KNOW?

IM Regulatory Newsletter

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What is Complion and how can I use it to help with my research?

What is Complion?

Complion is the electronic regulatory system platform for all clinical trials at the University of Cincinnati and UC Health as per UC Health SOP# UCH-OCR-OPS-SOP-016-01.

According to regulations, it is the site's responsibility to meet regulatory criteria, and as such, a standard mechanism to create, maintain and store clinical trial regulatory documentation. Effective July 2019, our institution designated the Complion eRegulatory system as the platform utilized for this purpose.

All research studies done at the University of Cincinnati and UC Health are to utilize Complion as the eRegulatory filing system for maintaining and archiving all Regulatory documentation for studies beginning July 2019 and thereafter. This includes retrospective chart reviews, observational studies, and trainee research. Only studies that are deemed exempt or Non-Human Subject Research (NHSR) by the IRB of record are not required to have a Complion study binder.

What are the benefits of using Complion?

NO MORE PAPER BINDERS!

- All regulatory documents are housed in the Complion study binder from start to finish
- Remote monitoring available at any time
- 21 CFR Part 11 Compliant
- Easy signing of delegation logs, training logs and UC COI forms
- Instant access for entire research team to see current approved protocol, current consent, current manuals, current IBs and package inserts as well as sponsor correspondence
- Study team credentials are maintained in one central binder and pulled into each study binder
- Lab certifications are maintained in one central binder and pulled into each study binder
- Archiving within Complion – allowing for easy retrieval and eliminates off site storage

Complion can be used as your shared drive in terms of knowing:

- What protocol version is currently approved by the IRB?
- What is the current IRB approved consent form?

For more information on how to best use Complion for your clinical needs, please contact us!

If you have any questions, please do not hesitate to reach out to: IMRegulatory@uc.edu

For more information, please click: [Tools and Templates](#)

Thank you!