|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Patient[[1]](#footnote-1) | Site[[2]](#footnote-2) | CRO[[3]](#footnote-3) | Sponsor[[4]](#footnote-4) | Regulator[[5]](#footnote-5) |

MVP showing a basic implementation of a module for each level of party involved (depending on time constraints may need to by less). Ultimately each module would scale laterally for a production case but demonstrating efficacy at each level of oversight and the ability to scale would be very high impact.

Delegation of Authority Log

TBD

Drug Accountability

Regulatory Document Log

Informed Consent Log

1. Volunteers for the Clinical Trial [↑](#footnote-ref-1)
2. Usually a medical facility, hospital, or clinic [↑](#footnote-ref-2)
3. Contract Research Organization; contracted by the sponsor to conduct, manage, and audit the study [↑](#footnote-ref-3)
4. Generally a biotech/pharma company, academic institution, or occasionally government funded entity [↑](#footnote-ref-4)
5. FDA for the US and EMA for the EU [↑](#footnote-ref-5)