

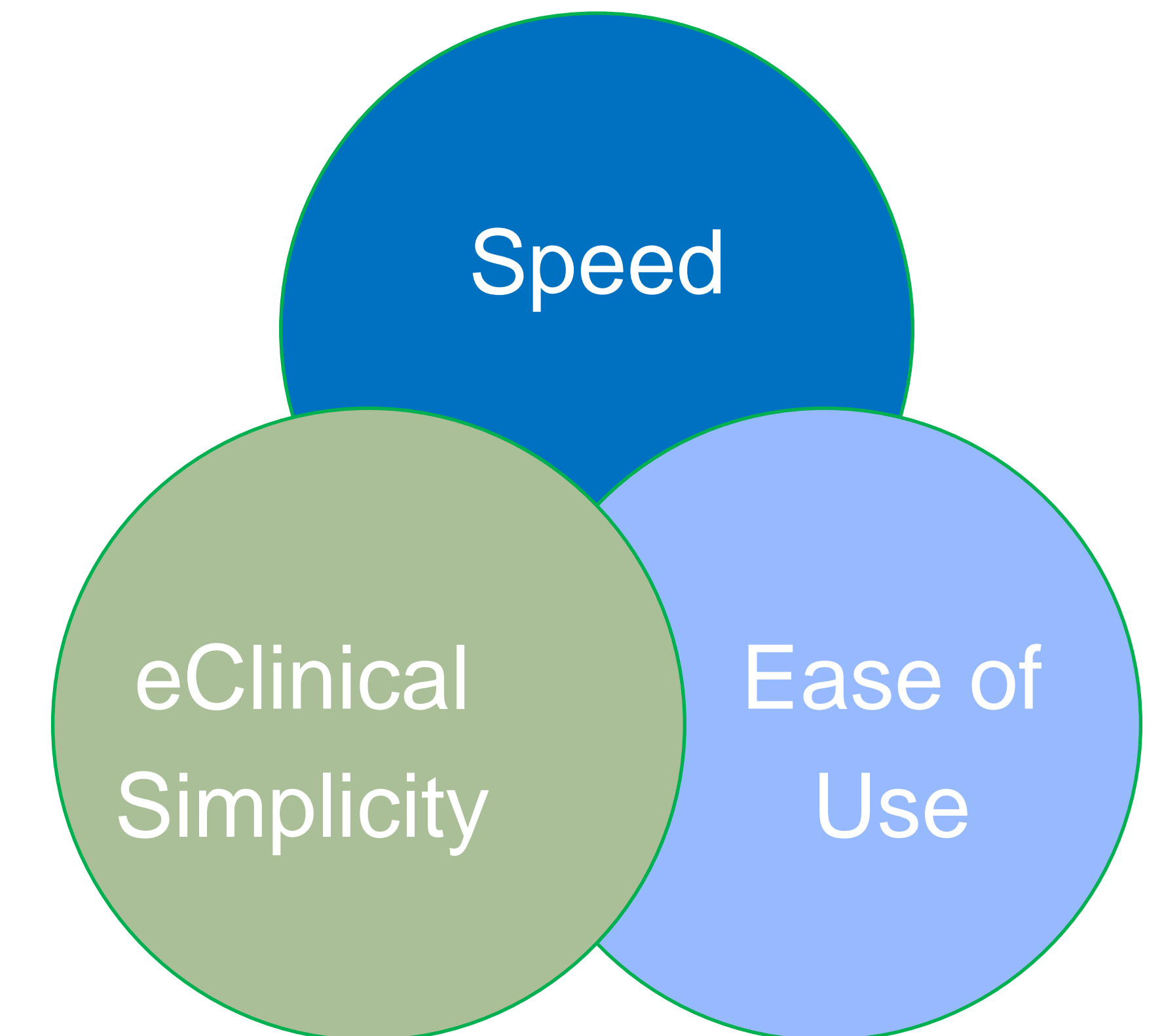
# Building an Electronic Data Capture (EDC) System for Investigator Initiated Trials

## Description of the Problem

The Phase 1 Program at the Seattle Cancer Care Alliance has opened several complex, investigator-initiated trials with a need for a more sophisticated electronic data capture system. The system needed to be fast, flexible, and easy to build without hiring programming contractors. The system should also have the ability to generate and resolve queries and provide real-time data sharing. Furthermore, the system should be able to handle mid-study changes with minimal downtime while being reliable and easy to use for data entry users, Clinical Research Associates, and Principal Investigators.

## BEST PRACTICE STRATEGY:

After researching few available EDC options, the Phase 1 Program moved forward with an eClinical tool, Medrio that best suited its needs and provided the training materials necessary to accurately and independently build the EDC. Medrio offered the power to control and create unique, study-specific case report forms (CRF's) with no reliance on vendors or contractors. It provided the speed we needed to build our CRF's and has an easy to use interface.



## Outcomes

Developing and building our own EDC using Medrio has been extremely successful for our program and partnering sites. Creating form rules like edit checks and skip logics has allowed us to enter data rapidly while ensuring accuracy. We can quickly run specific reports to look at query resolution, enrollment progress, review adverse events and ensure that the study is moving along according to its timeline. Successful implementation of Medrio by the Phase 1 Program contributed to increased interest in collaborations on investigator-initiated trials. Additional Medical Oncology research teams elected to switch to Medrio after learning about its superior capabilities.

## Best Practice Methods to Build a Successful EDC

- ▶ Review the protocol requirements and create a list of CRF's
- ▶ Meet with the Principal Investigator to discuss data points that would be useful for reporting and the data collection needs for the trial
- ▶ Configure your study by entering general study and formatting information, participating sites, cohorts, randomization and monitoring steps
- ▶ Configure your unique CRF's, create form skip logics and rules
- ▶ Deploy to test environment and test all forms for accuracy by entering test data for at least 5 subjects
- ▶ After successful completion of testing, review forms with the Principal Investigator, Regulatory and Clinical Coordinator team to get final approval
- ▶ Create EDC Data Entry Guidelines for site users
- ▶ Train and document training for all required users and provide them access to the EDC
- ▶ Save data dictionary and deploy to live environment
- ▶ Deploy any amendment changes as needed and inform all site users

### Acknowledgements

Medrio EDC