Utilizing Artificial Intelligence for Efficient CRF Design

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Komal Govil, Senior Global Data Manager
Sai Vundela, Senior Global Data Manager

Donna Williams, Discovery
Donna Williams, an autistic artist, author and renowned autism advocate, was diagnosed with breast cancer in 2011.
Agenda

- CRF Design
  - What is a Case Report Form?
  - Current CRF Design Process
  - Current Challenges with CRF Design

- Artificial Intelligence
  - What is Artificial Intelligence?
  - Recommender Systems
  - User and Item Profiles: A Hybrid Approach

- The Approach
  - Objective
  - Decision Tree Classifier
  - Training and Testing the Algorithm

- Cost Benefit Analysis
- Conclusion
CRF Design

What is a CRF?
Current Design Process
Challenges with Current Process
What is a Case Report Form (CRF)?

- Used to collect patient data in a clinical trial
- Data management manages the logistics of data collection and data delivery
CRF Draft Design Process

Understanding the protocol

Time and events schedule

Creating an initial list

Checking in libraries

Extract first draft
Standard Libraries

- Global
- Therapeutic area
- Disease area
- Compound
Challenges with Current Process

- Authorities require draft CRFs early in the process
- Large standard libraries are slow to adapt
- Complicated protocols create delays
- CRF design is time consuming
- Current processes are manual and inefficient
Artificial Intelligence

What is Artificial Intelligence?
What is a Recommender System?
User and Item Profiles
Automation

- Explicit rules
  - Good for repetitive tasks

Artificial Intelligence

- Learns rules
  - Can be generalized
Recommender Systems

Collaborative
- Based on Users
- Friend suggestions

Content based
- Based on Items
- Song suggestions
Profiles

User profile

Study Protocol

Item profile

Standard CRF
Approach

Objective
Decision Tree Classifier
Training and Testing the Algorithm
Objective

Initial draft CRF
Decision Tree Classifier

Is this form used for all protocols?

Include the following forms: Subject ID, Inclusion/Exclusion Criteria, Date of Visit etc.

Is the protocol a part of the oncology therapeutic area?

Also include the following forms: Diagnosis Form, Evaluation of Response

Is the indication a heme malignancy or a solid tumor?
Training and Testing the Algorithm

6 Oncology Protocols → Standard CRF → 4 Train 2 Test → Algorithm → Draft CRF
Cost Benefit Analysis
Pros

- Cost efficient in the long run
- Reduces the design time
- Adaptability streamlines the CRF design process
- Eliminates unproductive tasks
- CRF design is based on the most recent standard libraries
- Front-end and back-end edit checks can be carried over with the CRF
- UAT time will be reduced if using preconfigured libraries

Cons

- Manual intervention still needed
- Unique forms need to be designed
- Creating and developing algorithm requires initial investment of resources
Conclusion
Next Steps

Focusing on a limited number of protocols and on the global library, will aid implementation in the beginning

- We can expand the program to take in more protocols
- Therapeutic area and compound specific standard eCRFs
- Field level rather than a form level
- Quickly adapting CRF standards based on current trends
Thank you

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