



Utilizing Artificial Intelligence for Efficient CRF Design

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Donna Williams, an autistic artist, author
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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

Subject: Subject
Page: Demographics

Did the subject first sign a pre-screening consent for [protocol-specific test name]? ☐ Yes ☐ No

If Yes, what was the date of signature on [protocol-specific test name]? ...

INFORMED CONSENT

What was the date of the signature on informed consent? ...

INFORMED ASSENT

What was the date of signature on informed assent? ...

PROTOCOL DATE

What was the issue/report date of the protocol the subject consented to at study enrollment? ...

DEMOGRAPHICS

What is the subject's age?

Age unit

What is the sex of the subject?

☐ Female
☐ Male
☐ Unknown
☐ Undifferentiated

What is the ethnicity of the subject?

☐ Hispanic or Latino
☐ Not Hispanic or Latino
☐ Not Reported

CRF Draft Design Process

Understanding the protocol



```
graph TD; A[Understanding the protocol] --> B[Time and events schedule]; B --> C[Creating an initial list]; C --> D[Checking in libraries]; D --> E[Extract first draft];
```

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

Content based

Based on
Users

Friend
suggestions

Based on
Items

Song
suggestions

Profiles

User profile
Study
Protocol

Item profile
Standard
CRF

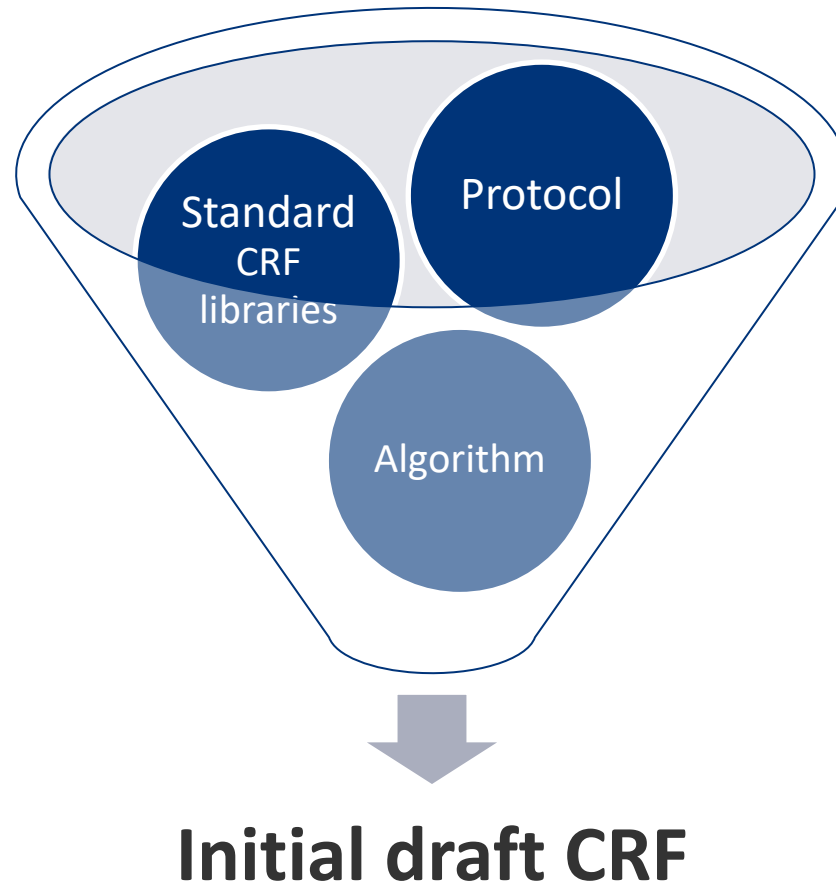
Approach

Objective

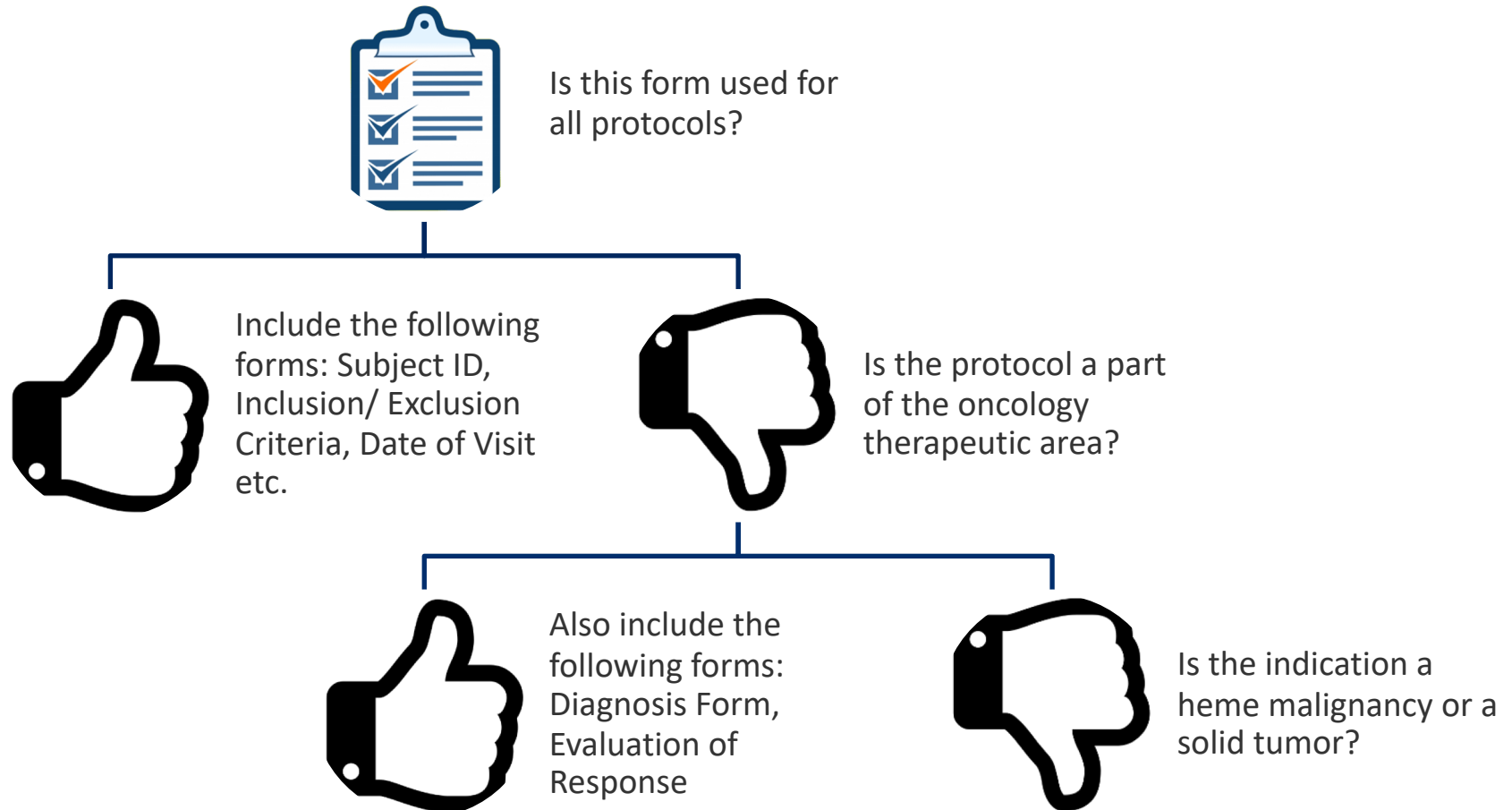
Decision Tree Classifier

Training and Testing the Algorithm

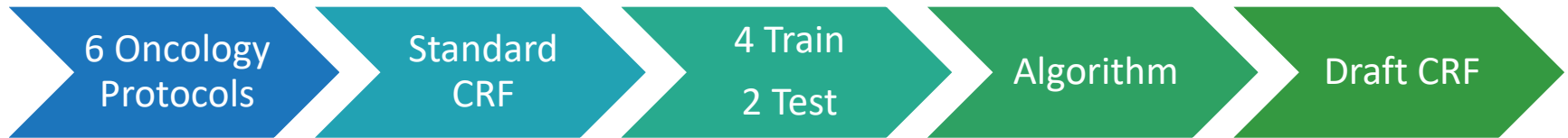
Objective



Decision Tree Classifier



Training and Testing the Algorithm



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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