Protocol Builder Feasibility Analysis

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Introduction

- Secure, web-based application to help Institutions create better quality investigator-initiated protocols faster and easier
- Developed by BRANY (Biomedical Research Alliance of New York)
- Designed to meet Federal/Industry Regulatory Standards
  - *16 various Protocol Types – Observation and Interventional*
  - *Expert Guidance icon – Detailed explanation of the requirements for each field*
  - *Smart Forms with Branching Logic – Predictive and reduces the need for double-entry of text*
  - *Resource Center – Provides commonly used Research forms and allows addition of supporting documentation*
- Allows for development and review of document protocol by multiple individuals (Investigators, Coordinators, Administration, etc.)

Studies Evaluated

- 8 IRB-reviewed, Investigator-initiated Studies
  - *Experienced Investigators purposely selected*
  - *Interventional FDA -Approved Drug/Biologic (2); Interventional FDA-approved drug w/repository (1); Interventional Drug - Investigational New Drug (2); Interventional Device - Non Sig. Risk (1); Observational Prospective (1); Interventional Behavioral (1)*

Federally Funded (*NIH - NIDDK, NCI, NHGRI, NICHD*)

- Adoptive Transfer of Cord Blood T cells to Prevent and Treat CMV, EBV and Adenovirus Infections after Transplantation
- Multivirus-Specific Cytotoxic T-Lymphocytes for the Prophylaxis and Treatment of EBV, CMV, and Adenovirus Infections post Allogeneic Stem Cell Transplant
- Energy Expenditure and Metabolic Control Among Youth with T1 Diabetes
- Healthy Eating, Physical Activity, & Glycemic Control in Young Children with Type 1 diabetes (T1D) – Phase 1
- N-carbamylglutamate in the Treatment of Hyperammonemia
- Short-Term Outcome of N-Carbamylglutamate in the Treatment of Acute Hyperammonemia
- Reverse Transcriptase Inhibitors in Aicardi Goutières Syndrome

Internally Funded

- Integrated Control and Movement System to Enhance Flexible Ureteroscopy

Categories Evaluated

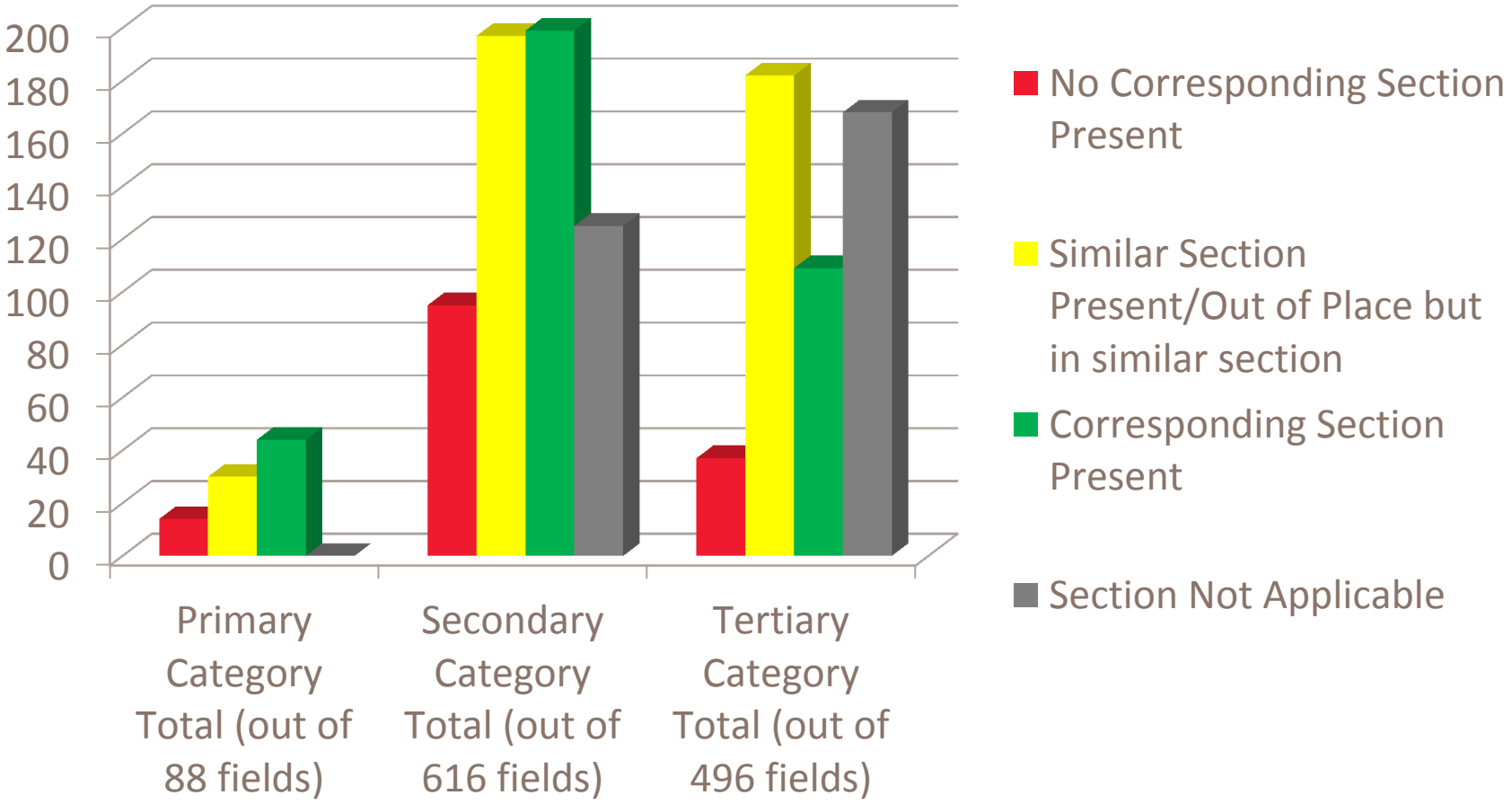
- User Interface contains 150 total fields
  - *Number of fields per study dependent upon Protocol Type selected*
  - *11 Primary fields – Cover Page, Synopsis, Introduction, Study Objectives, Study Design, references, etc.*
  - *77 Secondary fields – Title, Investigational Product, Prior Experience, Risks/Benefits, Outcome Variables, Study Population, Funding Source, etc.*
  - *62 Tertiary fields – Drug/Device Preclinical Experience, Primary Outcome Variable, Eligibility Criteria, Adverse Events Definition, etc.*

- Feasibility Study (N=8)
  - *88 total Primary fields; 616 total secondary fields; 496 total Tertiary fields*
  - *Investigator's official Protocol compared to associated fields within Protocol Builder*

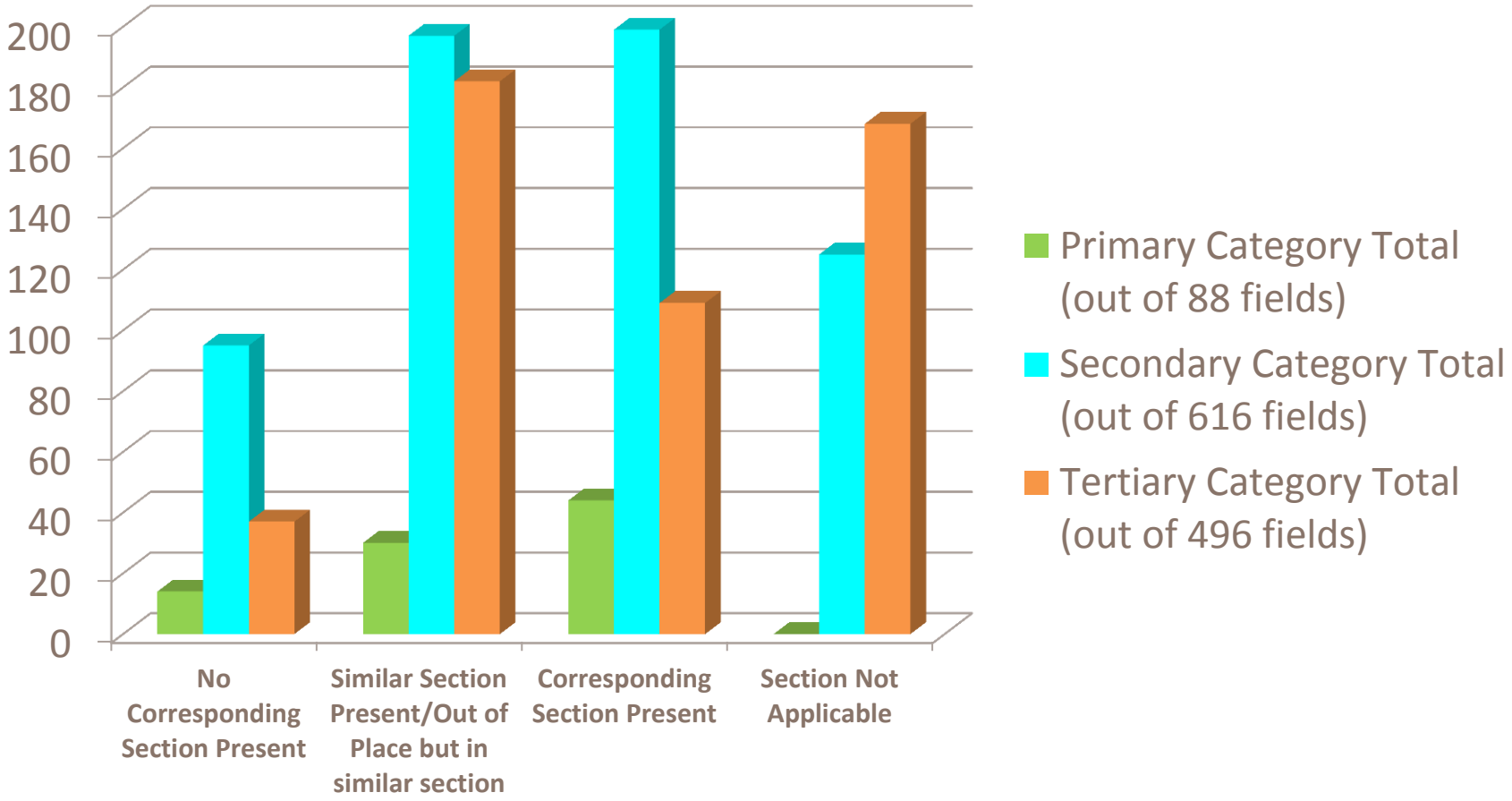
Key

- *No Corresponding Section Present*
- *Similar Section Present/Out of Place but in similar section*
- *Corresponding Section Present*
- *Section Not Applicable*

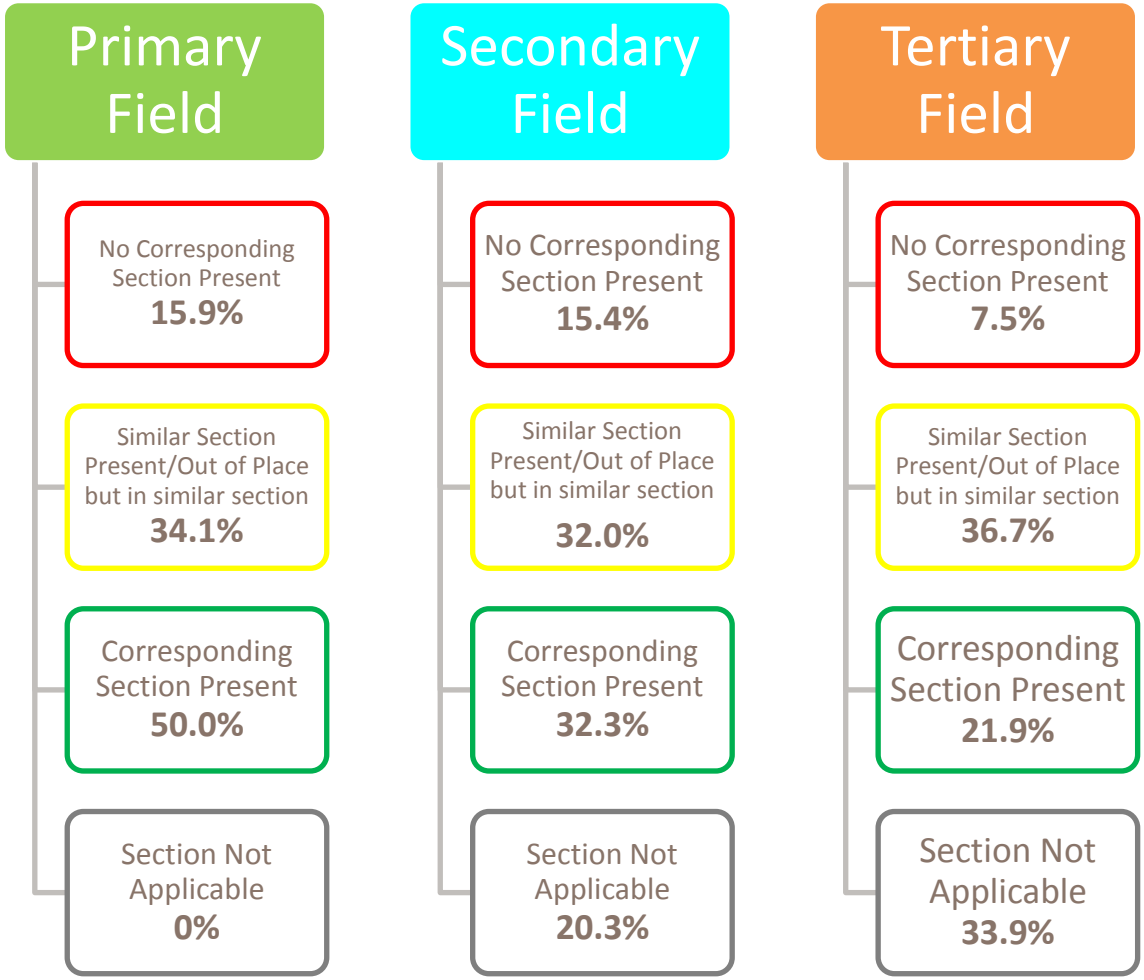
Results 1



Results 2



Findings



Findings

- Overall the majority of Primary, Secondary, and Tertiary fields are present
- **However…**

1) *A significant number are out of place or placed inconsistently throughout the protocol (i.e. there is very little organizational consistency among protocols)*
2) *Many of the sections that are missing are essential* (e.g. Protocol version/date; Adverse Events definition and reporting; IRB Review; Removal of subjects; Study discontinuation; Study monitoring; Handing of missing data; Appendix/References, etc.)

- Drug/Biologics studies (both FDA-approved and IND) are most consistent; Observational/Behavioral least consistent
- Studies reviewed and approved by NIH were most consistent

Benefits/Considerations

- Benefits
  - *Quality Improvement*
    - Improve consistency of protocol development institution-wide
    - Increase adherence to FDA, IRB, Sponsor, and Institutional regulations
  - *Expedite Process*
    - Guided experience saves Investigator's time
    - Standardization decreases time and effort required for SRC, IRB, etc. review
  - *Automatic Updates*
    - Continuously updated to address changes in regulations, industry standards, and research trends
  - *Web accessibility*
    - Accessible anywhere, anytime
- Considerations
  - *Cost*
  - *Adding a writer or reviewer to a protocol requires the use of an additional license*
  - *Current format may require some modifications to suit Institutional norms*

Recommendations

- Should be considered a template protocol development tool
  - *Not final – Minor modifications can be made after completion to suit Sponsor, IRB, etc.*
- Conduct a 15 - 25 study pilot including junior and senior Researchers
  - *To confirm need and to obtain feedback (esp. regarding user interface changes)*
- Review of input fields by CNHS Research experts (Select senior Investigators, OPHS, QA/QI staff, etc.)
  - *Developers can modify user interface and input fields based on client feedback*
  - *Consider adding: Confidentiality statement; Signature page; "N/A" option*
  - *Consider omitting: Study number; funding source; Health Economic Impact*
- Ad hoc modifications be allowable in contract