About Us: Clinical Research Unit

- Mandate to support investigator initiated clinical research
- Support Centre housed in U of C Cumming School of Medicine supporting:
  - Medicine
  - Kinesiology
  - Nursing
  - Veterinary Medicine
- Technology first approach to support
  - Small pool of staff that touch study data in an ongoing fashion
    - 3 Data managers
    - 2 Statisticians
    - 2 Unblinded Stakeholders
  - Everyone else is Projects, Operations or Technical Staff (SA, DBA, Developer

<table>
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<tr>
<th>Project Type</th>
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<td>Methods and Analytics</td>
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About Us: B153 Ltd.

- Founded by Clinical Research Unit staff in early 2018
- Working with U of C, Cumming School of Medicine, Clinical Research Unit, Cumming School of Medicine, Innovate Calgary
- Project 1, is to make the tools referred to as Study Manager commercially available
- A focus to support development of the products and IP licensed from University of Calgary to B153 to independent commercial entities
Today

- History and current state of our Study Manager platform
- Loose roadmap and plans for our Study Manager Platform
- Ask the group here today for help with something
Study Manager History

- First deployment in 2013 for Escape Trial.

- Five RCT deployments since
  - Tempo 1 (Stroke. 2015 Mar;46(3):769-74)
  - Tempo 2 (1/3rd Complete)
  - Dose (Complete)
  - Escape-NA1 (1/3rd Complete)
  - Perk 2 (Deployed today!)

- Two pragmatic trial deployments in development.
  - QuICR and Optimize
Study Manager History

- Feature Buildout (Escape)
  - Novel randomization algorithm
  - Central document approval
  - Recruitment notifier
  - Populated PDF as ‘source’ output
  - Small validation burden, just algorithm and software tests
### Subject Information

#### Inclusion Criteria:
- Age 18 years or older and skeletally mature
- Distal humerus (AO/OTA type 13) and/or proximal ulna and/or proximal radius fractures (AO/OTA type 21) and/or elbow dislocations (open fractures with or without nerve injury may be included)
- Injuries within 7 days or less
- Operative treatment of the elbow fracture or dislocation
- Subject has negative urine pregnancy test

#### Exclusion Criteria:

#### Confirm Eligibility and Consent:
- Eligible for study?
- Consented for study?
Study Manager History

- Feature Buildout (Tempo 1|2 and Dose)
  - Central Document Management tied to roles
  - Document History and Approval Views
  - Randomization + pharmacy notification
Study Manager History

- Feature Buildout (Escape NA1)
  - Full double blinded drug management workflows
  - Validated software system
  - CRO support… Inventive Health TMF Assembly
  - Study, Site and Staff level (role) documentation requirements
  - Site payment management based on data quality
## Finance - Subjects

### Site

Site: 01-PLC

### Subject(s)

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Study Manager History

- Feature Buildout (PERK 2)
  - User profile extension
  - Role, site and study level documentation compliance based targeted revocation of permissions
  - Software housekeeping, architectural and release management
Site Not Valid

Site FMC is not yet validated for randomization.
Please ensure that the site’s status is set to ‘active’ and all qualification requirements are complete and approved.

Required Certifications:

- Field: Ethic approved consent forms
  - Certification Form: Ethic approved consent forms

- Field: Ethic approval
  - Certification Form: Ethic approval

- Field: Protocol Signature Page (Signed)
  - Certification Form: Protocol Signature Page (Signed)

- Field: HRPO (site specific) approval
  - Certification Form: HRPO (site specific) approval

- Field: Site specific advertisements/brochures
  - Certification Form: Site specific advertisements/brochures
Roadmap

- Extend types of study design
- Generalize workflows
- Multi-tenancy
- Cross study personnel profiles
- Deeper integration with DF tools via API
- SAAS/Self service deployment
- TMF 3.0 baseline as documentation standard
- Full validation
Our Ask

- We’d like to identify a small group of outside eyeballs to (eventually) form a product development feedback pool.

- Email us: admin@b153.ca or visit with Mark, Andrea, Ashley or Craig while we’re here today and tomorrow.
Mark Lowerison,
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University of Calgary Clinical Research Unit
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