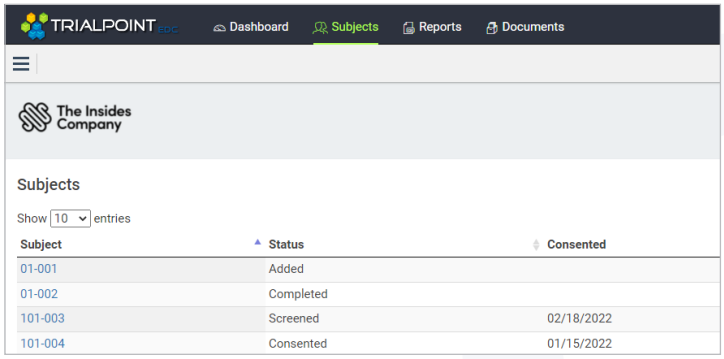
The Insides Company™

International Chyme Reinfusion Clinical Data Registry



- World's first registry to document clinical & patient reported outcomes of chyme reinfusion
- Sponsored by The Insides™ Company, the leading provider of automated chyme reinfusion for intestinal failure (IF) & rehabilitation
- Chyme reinfusion is recommended by ASPEN & ESPEN for the nutritional support of Type 2 intestinal failure patients

The Objectives of the Chyme Reinfusion Registry are:

- Identify the impact of chyme reinfusion on parenteral, enteral and oral nutritional needs in patients
- Validate the safety and efficacy of chyme reinfusion
- Understand the relationship between patient quality of life and chyme reinfusion, before and after reversal

Inclusion Criteria

- Individuals with IF suitable for and being treated with chyme reinfusion
- Participants may be male or female and of any age.

Exclusion Criteria

- Subjects who are unable to understand the study protocol or unable to give informed consent, and have no legal representative
- Participants with IF not suitable to be treated with Chyme Reinfusion

What Data is Collected?

- Date and time of assessment
- Inpatient /outpatient?
- Weight
- PN/EN/Oral nutrition data
- Frequency of chyme reinfusion
- Document Anti-motility medication
- Lab test results (CBC, LFT, Trace Elements)
- QoL (EQ-5D, Stoma-QoL)
- Readmission/Adverse Events

Data Ownership & Privacy

- The Insides™ Company will retain full ownership and control of the data
- Centres can export the data which they enter into the registry
- The Registry will be GDPR and HIPAA compliant
- Requests for publication of registry data can be made to The Insides™ Company

Resources & Support

- The Insides™ Company will provide training on data entry and how to create reports
- The registry is currently available in English with the potential to adapt the electronic PRO to French

For more information, please contact clinical@insidescompany.com