LIVE WEBINAR

Insights from TÜV SÜD and Greenlight Guru on the Requirements of PMCF under the MDR 2017/745

March 19, 2024 | 10 am EDT/ 3 pm CET

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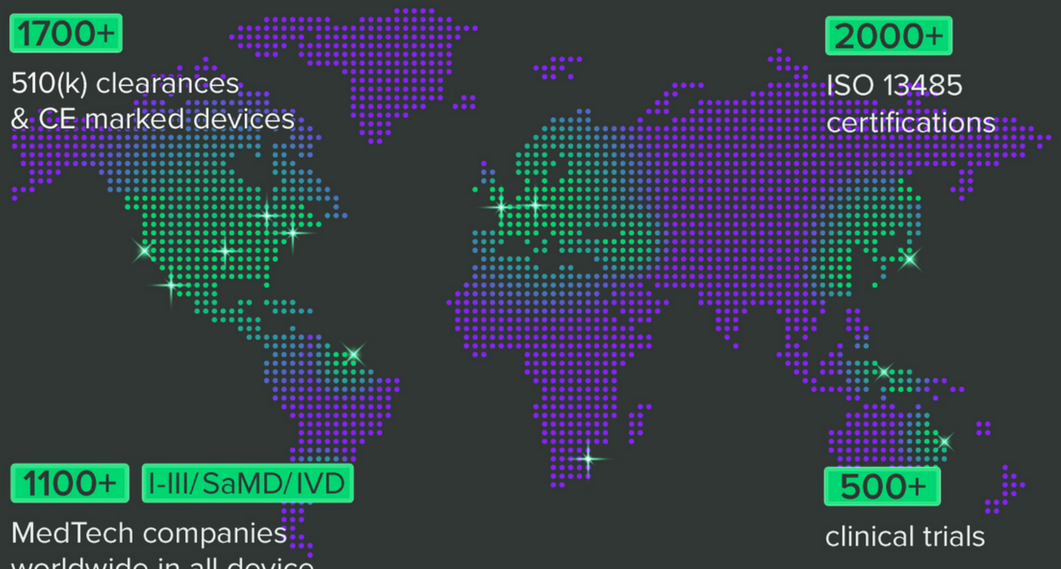

1700+
510(k) clearances & CE marked devices

2000+
ISO 13485 certifications

1100+ I-III/SaMD/IVD
MedTech companies worldwide in all device classes and types

500+
clinical trials

"Best QMS I have ever used..."

"User-friendly EDC and esponsive support team"

"This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry."

"The whole experience of using Greenlight Guru Clinical is accessible and user-friendly"

"Makes your QMS Simple and Effective"

Today’s Presenters

Chris Rush
Solutions Engineer,
Greenlight Guru

Dr. Rene Bombien
Chief Medical Officer,
TÜV SÜD, Denmark MHS

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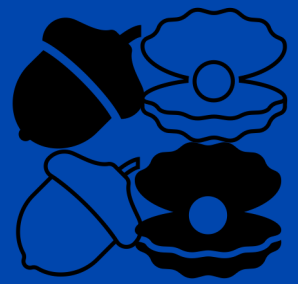
Post Market Clinical Follow-Up according to MDR 2017/745 and MDCG 2020-7 and 2020-8

René Bombien, Chief Medical Officer

2024-03-19

Add value.
Inspire trust.



PMCF

Annex XIV Part B

=

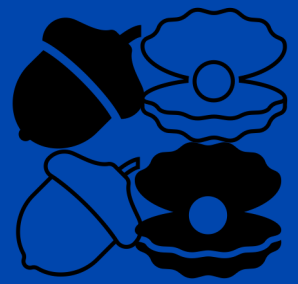
aim of confirming the safety and performance throughout the expected lifetime of the device

ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence

continuous process

updates the clinical evaluation

proactively collect and evaluate clinical data from the use in or on humans […] within its intended purpose



PMCF
Annex XIV Part B

PMCF Study

Alternatives

Specific Methods

Suitable Registry

Specific Methods

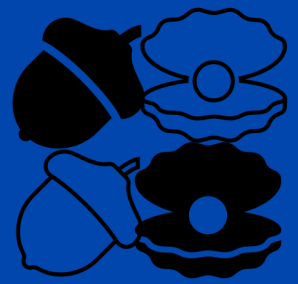
gathering of clinical experience gained

feedback from users

General Methods

screening of scientific literature

other sources of clinical data



PMCF

MDCG 2020-7 and 2020-8

MDCG 2020-7

Post-market clinical follow-up (PMCF) Plan Template
A guide for manufacturers and notified bodies

April 2020

Contents

MDCG 2020-8

Post-market clinical follow-up (PMCF) Evaluation Report Template
A guide for manufacturers and notified bodies

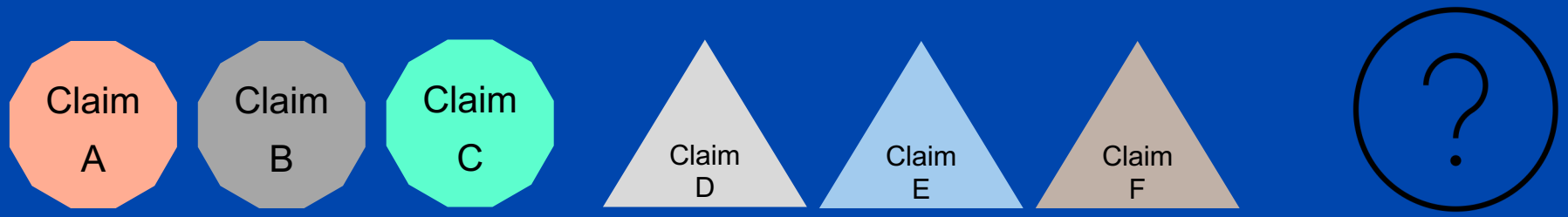
April 2020

Contents

PMCF

Annex XIV Part B

Conformity Assessment → PMS plan with PMCF → CER update



PMCF

Annex XIV Part B

Conformity Assessment → PMS plan with PMCF → CER update

Claim A | Claim B | Claim A | Claim B

PMCF

Annex XIV Part B

Conformity Assessment → PMS plan with PMCF → CER update

Claim
Permanent Implant

PMCF duration 24 month

Clinical development stages as per ISO 14155:2021

Regulatory status	**PRE-MARKET**		**POST-MARKET**	
Clinical development stage	Pilot stage	Pivotal stage	Post-market stage	
Type of design	Exploratory or confirmatory	Confirmatory		Observational
Descriptors of clinical investigations	First in human clinical investigation Early feasibility clinical investigation Traditional feasibility clinical investigation	Pivotal clinical investigation	Post market clinical investigation	Registry * Post market clinical investigation
Burden to subject	Interventional			Non Interventional
*Registry data may be used for pre-market regulatory purposes, this may also apply to the post market clinical investigation data.				

PMCF…

→ does always mean Post Market Clinical Follow Up.

→ does not always mean PMCF Study.

→ - there are *Alternatives* to a PMCF Study.

→ must be aligned with the intended purpose.

Thank you!

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Insights from Greenlight Guru on the Requirements of PMCF under the MDR 2017/745

Chris Rush
Solutions Engineer,
Greenlight Guru

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PMCF Activities

- General PMCF Activities
  - Literature screening, survey feedback
- Specific PMCF Activities
  - case reports, IIT, registries, PMCF studies, surveys

Specific PMCF activities

	PRE-MARKET			POST-MARKET	
Clinical Development Stage	**Pre-Clinical**	**Pilot**	**Pivotal**	**Post-Market Surveillance (PMS)**	
Type	Exploratory	Exploratory & Confirmatory	Confirmatory		Observational
Descriptors	- In-Vitro - In-Vivo - Bench-test	- First-in-Human - Pilot Study - Safety Study - Exploratory Study - Early/Traditional Feasibility Study - Proof-of-Concept - Investigator Initiated*	- Pre-Market CI/Study - Pivotal CI/Study - PMA CI/Study - Phase III Study	- Post-market CI/Study - Investigator Initiated* - PMCF Study - Post-Authorization Study (PAS) - Validation Study	- Post-Market CI/Study - PMCF Study - Investigator Initiated* - Registry - Survey - Case Series - Cohort - Post-Authorization Study (PAS)
Burden to Human Subject	**None**	**Interventional**			**Non-Interventional**

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Electronic Data Capture, ISO 14155:2020

- Requires any electronic system be validated “in order to evaluate the authenticity, accuracy, reliability, and consistent intended performance of the data system.”
- Ensure attributability, completeness, reliability, consistency, and logic of the data entered
- Ensure that data changes are documented and an audit trail is maintained
- Maintain a security system to prevent unauthorized use of data, both internally and externally

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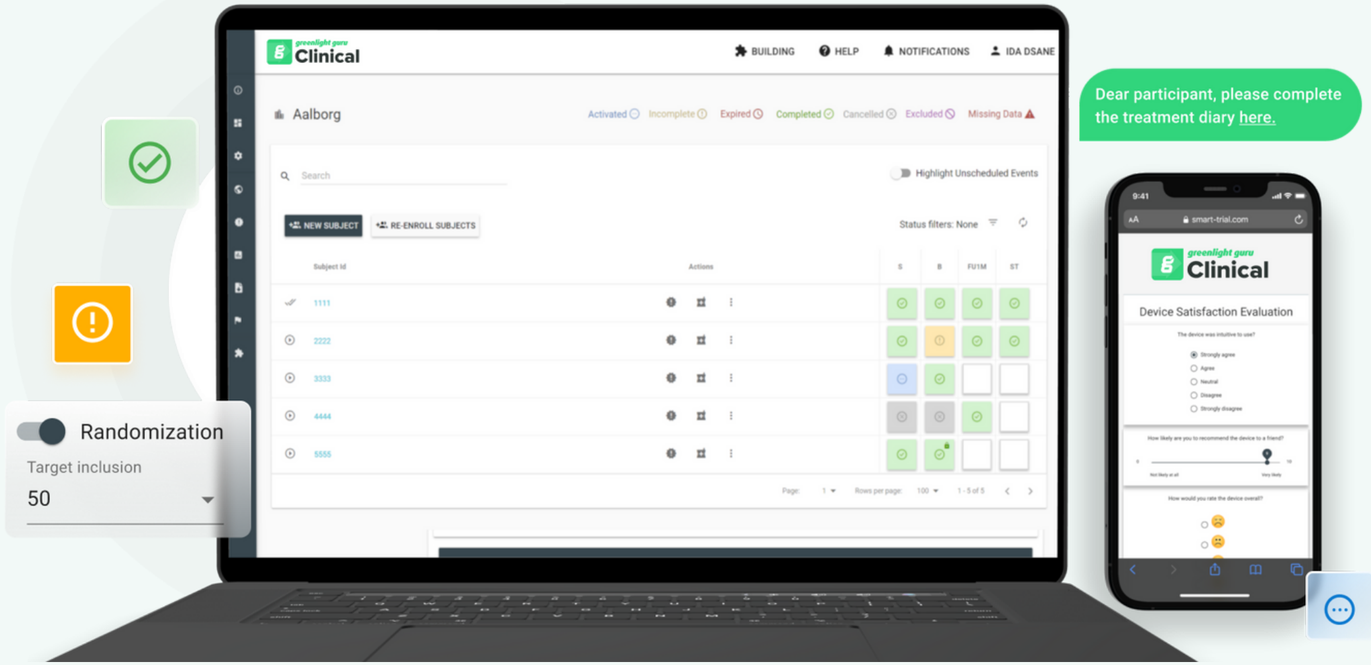
*Formerly **SMART-TRIAL***



The Leading Toolbox for MedTech Clinical Data Collection

A single, compliant platform for collection and management of all clinical evidence, safety, and performance data.

Learn more here: www.greenlight.guru/clinical

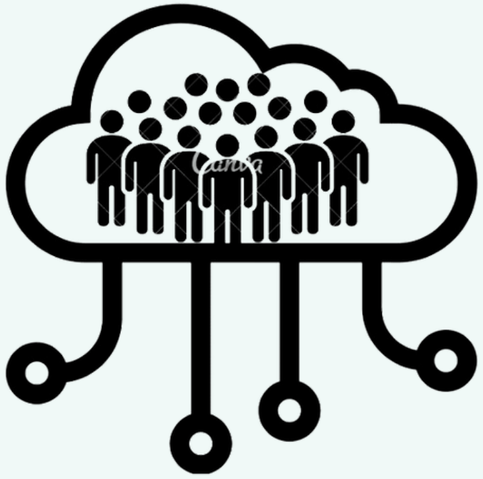
Subject Survey Studies

Public Survey Subject Database

Broad Subject Population

Survey/questionnaire

Quallified Subject Database



- If direct access to subjects is available, this is an option
- Data is subjective, so not applicable to all device types.
- Surveys may be subjective or subject-specific (but de-identified)
- Surveys provided to subjects via URL (online campaign), QR code

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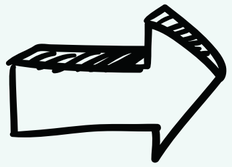
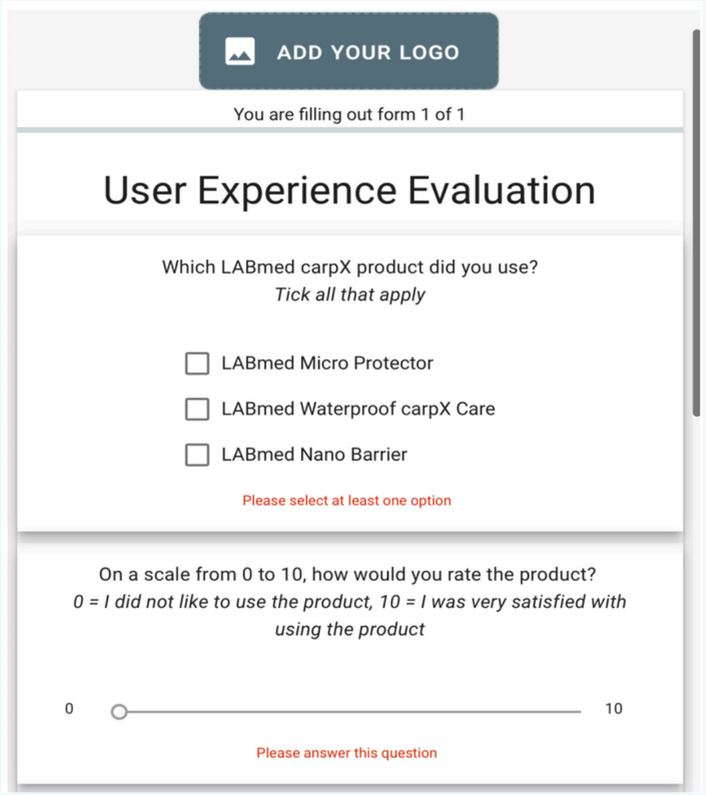
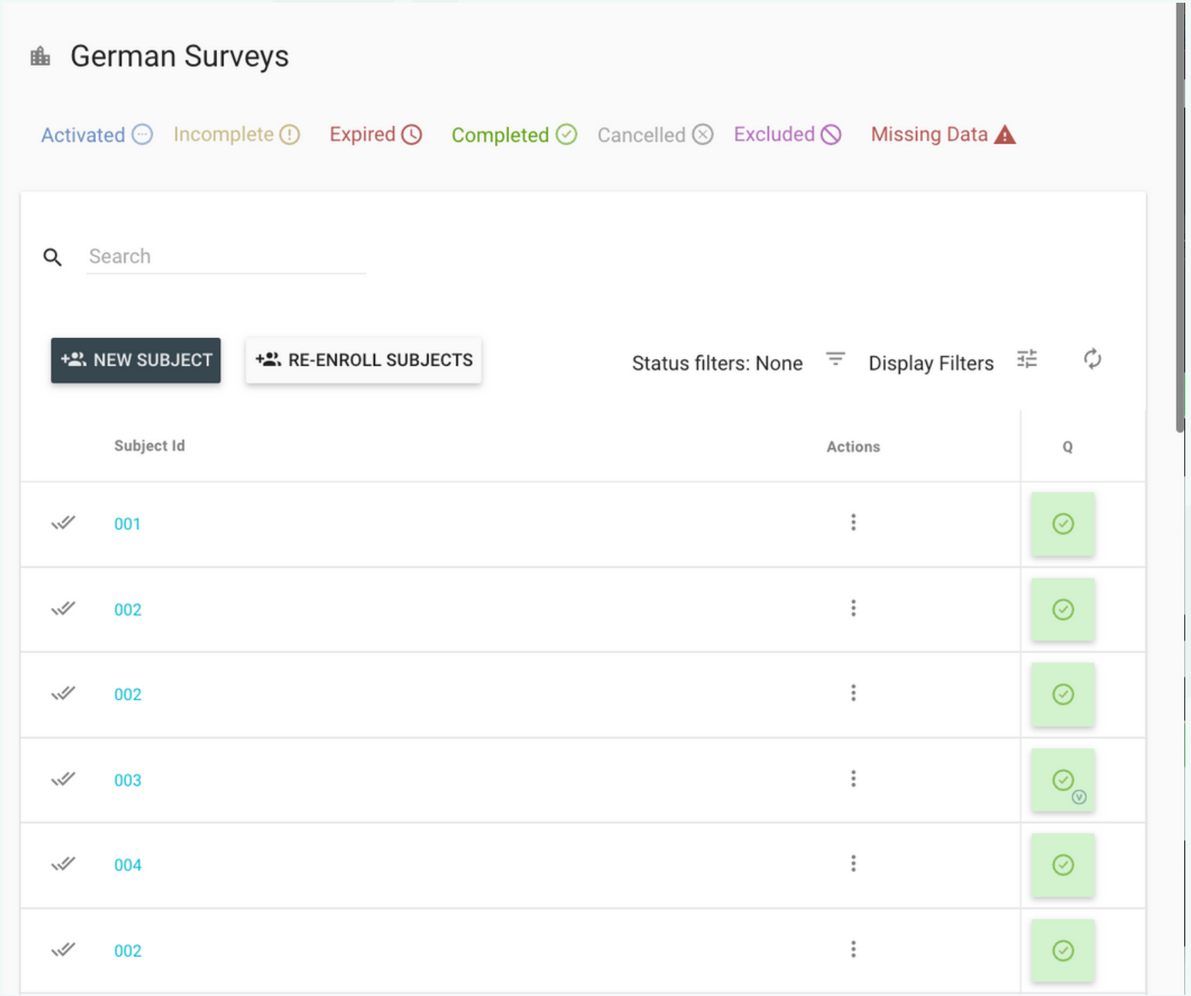
Subject Survey Studies

URL, QR Code







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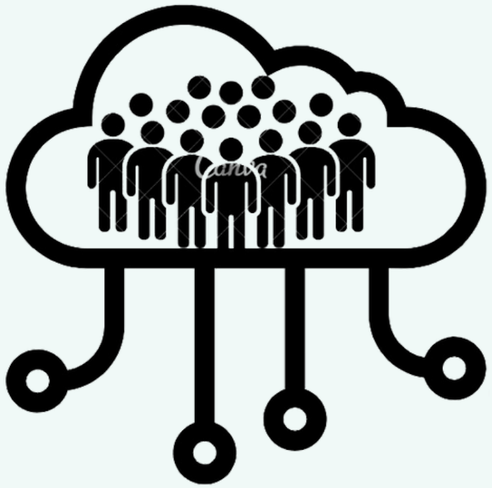
Physician Survey/Case Studies

Public Survey Clinician Database

Broad Clinician Population

Quallified Clinician Database



- If direct access to physicians is available, this is an option
  - ➡ Sometimes distributors stand in between
- Valuable, case-specific data
- Surveys/CR may be subjective or subject-specific (but de-identified)
- Surveys provided to subjects via URL (online campaign), QR code,
  - ➡ Sales reps, product managers
- May not be optimal for long-term follow-up (e.g. Class III)

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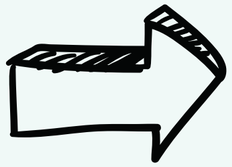
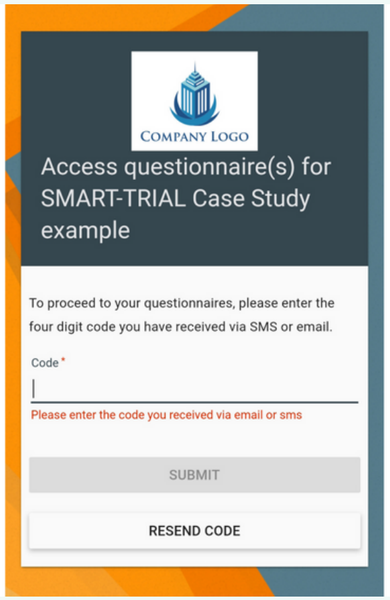
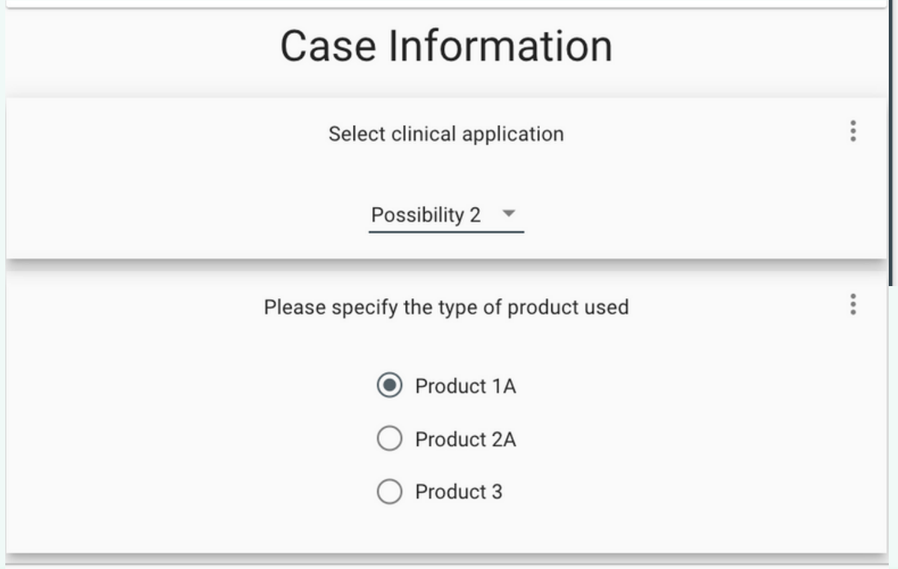
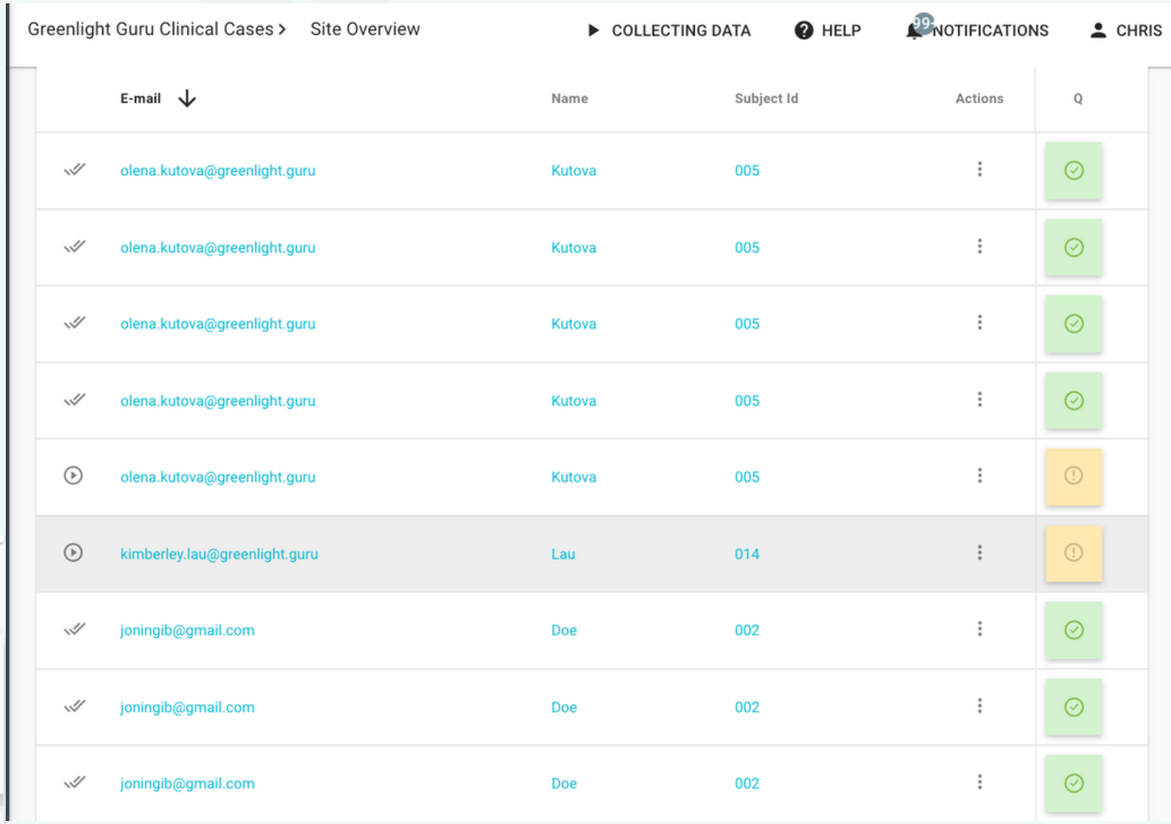
Physician Survey/Case Studies

URL, QR Code









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PMCF Studies, Registries, IITs

Traditional Screening and incl/excl

- Close control of data collection, endpoint definition
- High quality data captured per GCP requirements
- Very Common for Class III devices
- Requires time for follow-up, so other data is needed to support reporting

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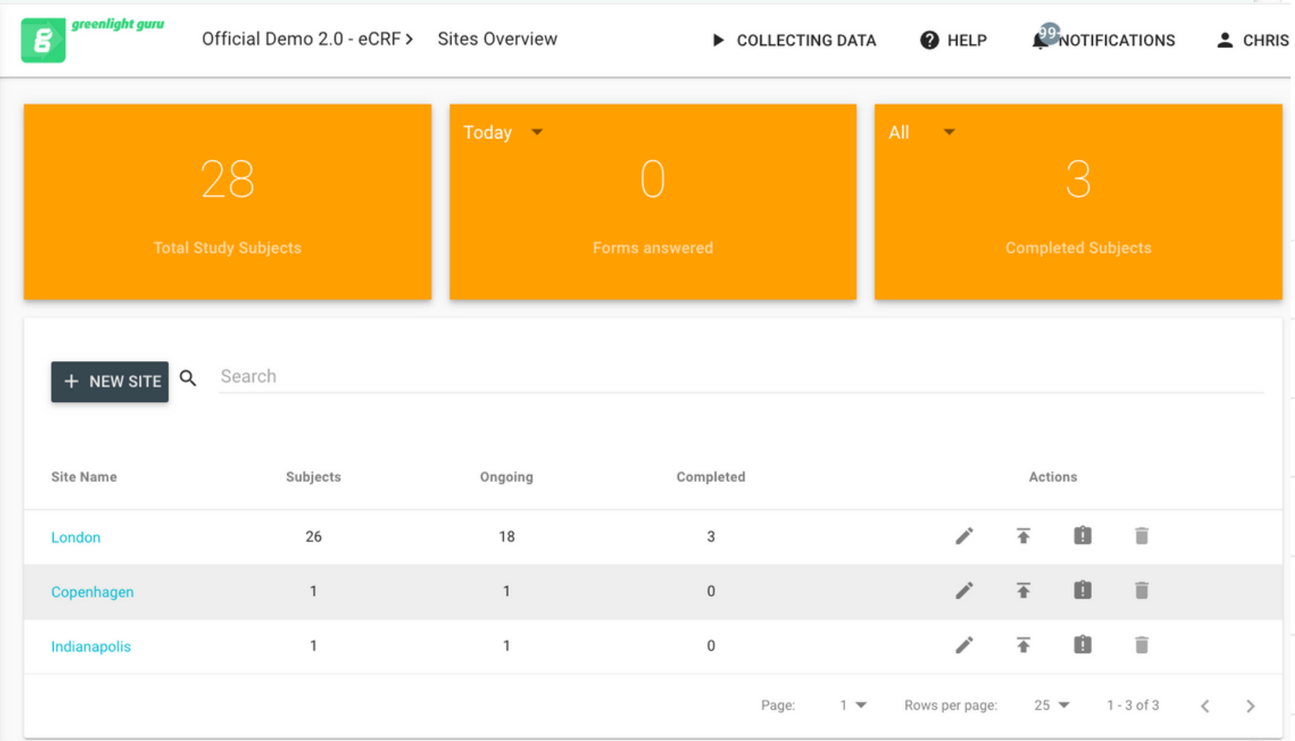
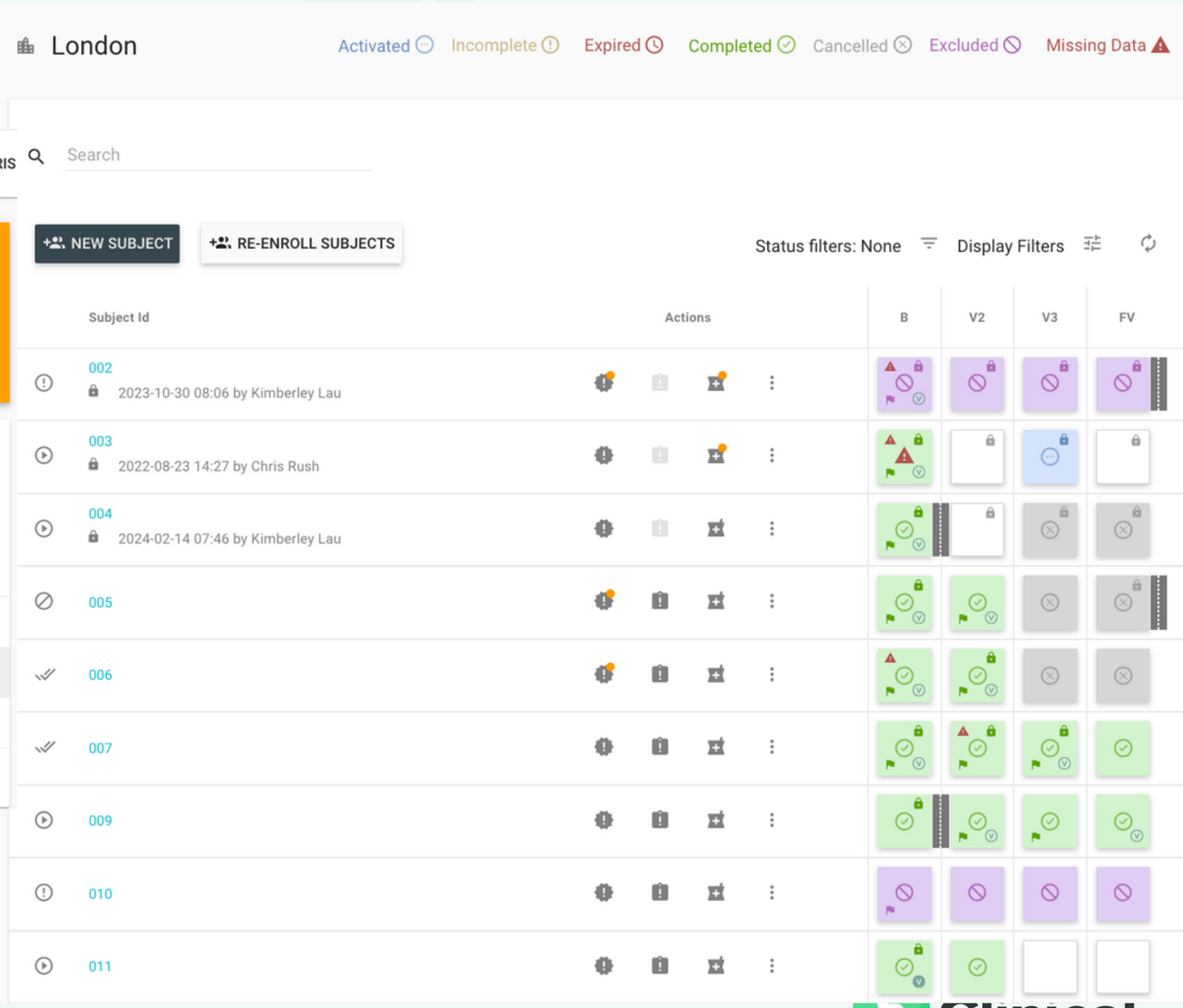
PMCF Studies, Registries, IITs





Clinical

PMCF Activities

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- Specific PMCF Activities
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Time for

Q&A

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