

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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MedTech companies
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classes and types

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“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

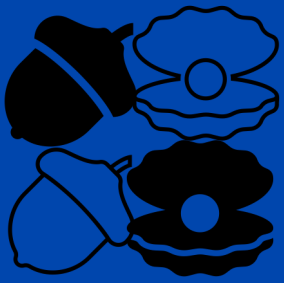


Post Market Clinical Follow-Up according to MDR 2017/745 and MDCG 2020-7 and 2020-8

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

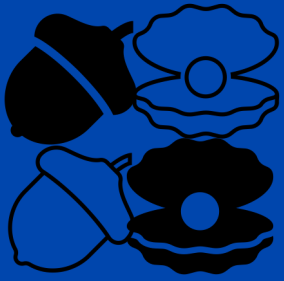
ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence

continuous process

updates the clinical evaluation

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





Specific Methods

Specific Methods

General Methods

PMCF
Annex XIV Part B

PMCF Study

Alternatives

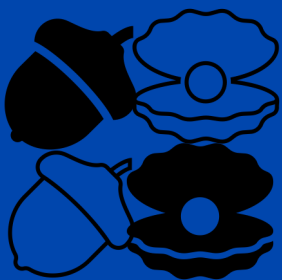
Suitable Registry

gathering of clinical experience gained

feedback from users

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

MDCG 2020-8

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

April 2020

Contents

Introduction.....	4
Post-market clinical follow-up plan Template.....	5
Section A. Manufacturer contact details.....	5
Section B. Medical Device description and specification.....	6
Section C. Activities related to PMCF: general and specific methods and procedures.....	7
Section D. Reference to the relevant parts of the technical documentation.....	9
Section E. Evaluation of clinical data relating to equivalent or similar devices.....	10
Section F. Reference to any applicable common specification(s), harmonized standard(s) or applicable guidance document(s).....	11
Section G. – Estimated date of the PMCF evaluation report.....	12

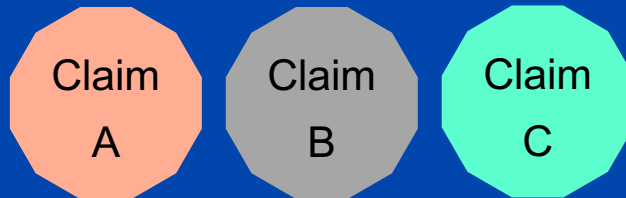
Contents

Introduction.....	4
Post-market clinical follow-up evaluation report Template.....	4
Section A. Manufacturer contact details.....	5
Section B. Medical Device description and specification.....	5
Section C. Activities undertaken related to PMCF: results.....	7
Section D. Evaluation of clinical data relating to equivalent or similar devices.....	7
Section E. Impact of the results on the technical documentation.....	7
Section F. Reference to any common specification(s), harmonized standard(s) or guidance document(s) applied.....	9
Section G. Conclusions.....	9

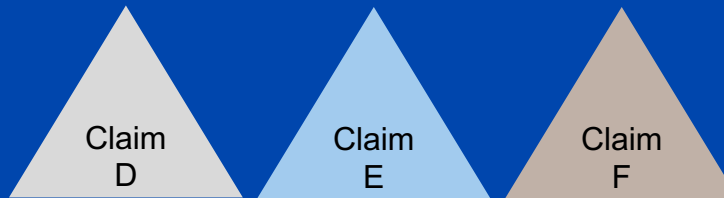
PMCF

Annex XIV Part B

Conformity Assessment



PMS plan with PMCF

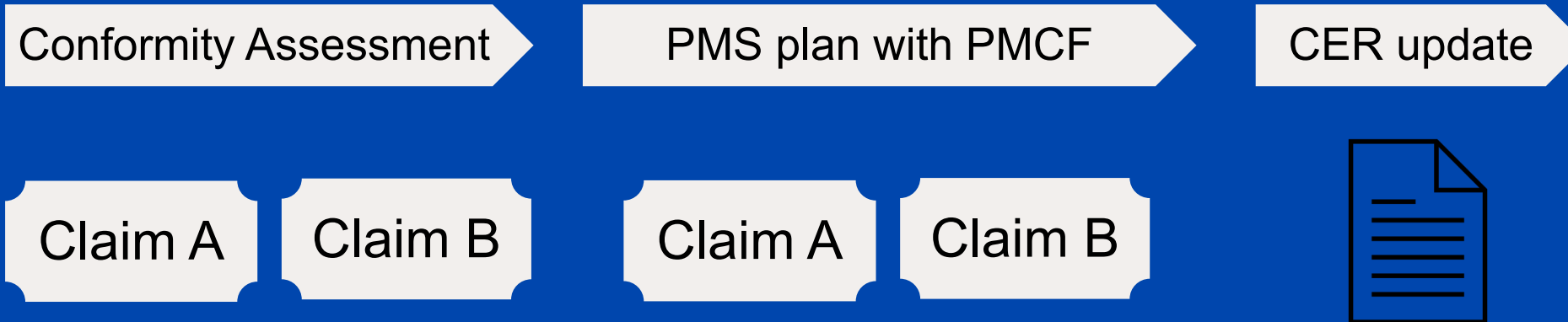


CER update



PMCF

Annex XIV Part 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

<i>Regulatory status</i>	PRE-MARKET		POST-MARKET	
<i>Clinical development stage</i>	Pilot stage	Pivotal stage	Post-market stage	
<i>Type of design</i>	Exploratory or confirmatory	Confirmatory		Observational
<i>Descriptors of clinical investigations</i>	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
<i>Burden to subject</i>	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!

Dr med habil René Bombien
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Chief Medical Officer
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Website: www.tuvsud.dk

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



Chris Rush
Solutions Engineer,
Greenlight Guru

PMCF Activities






- General PMCF Activities

- ➔ Literature screening, survey feedback

- Specific PMCF Activities

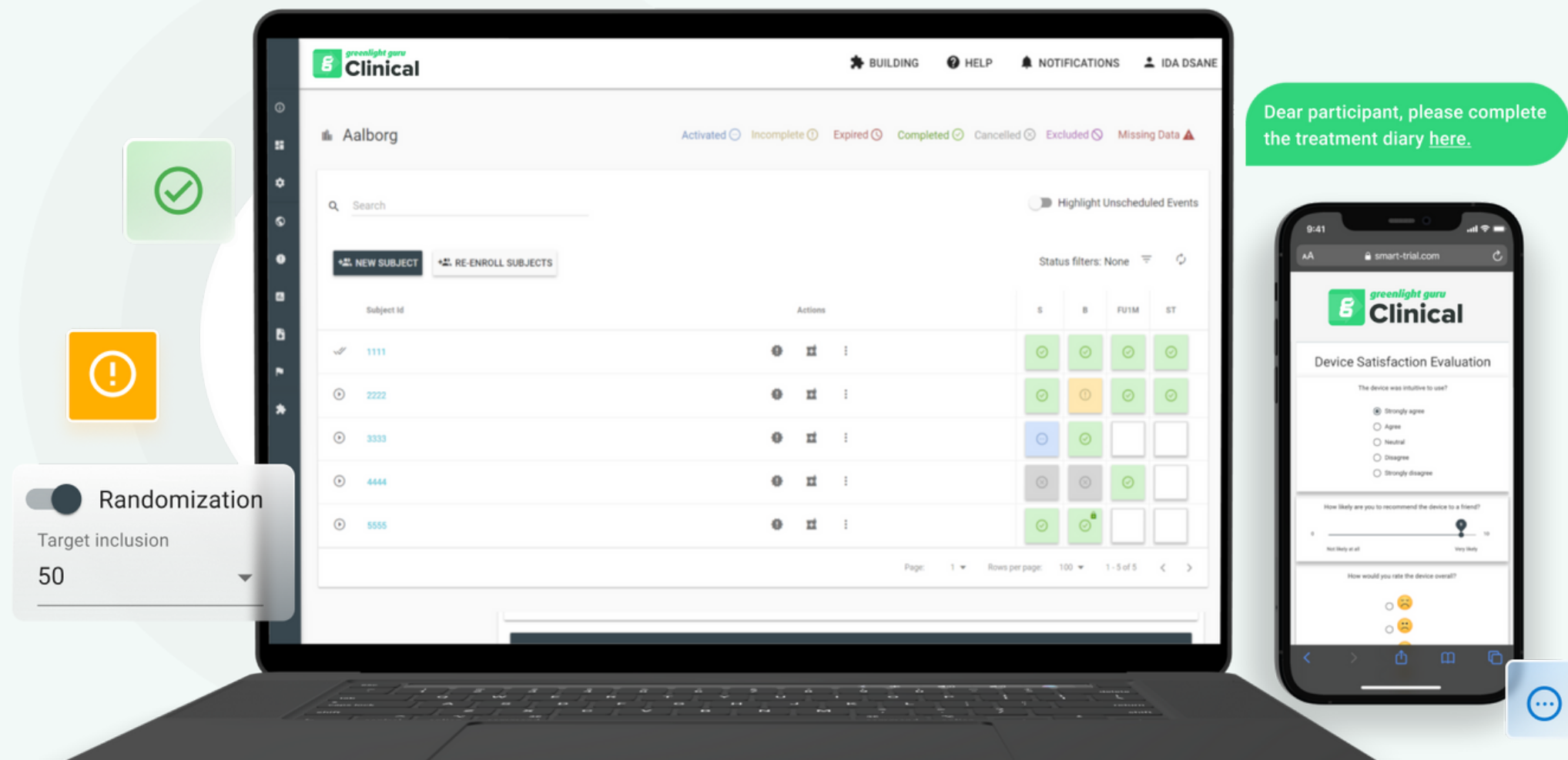
- ➔ case reports, IIT, registries, PMCF studies, surveys

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	 <ul style="list-style-type: none"> - In-Vitro - In-Vivo - Bench-test 	 <ul style="list-style-type: none"> - First-in-Human - Pilot Study - Safety Study - Exploratory Study - Early/Traditional Feasibility Study - Proof-of-Concept - Investigator Initiated* 	 <ul style="list-style-type: none"> - Pre-Market CI/Study - Pivotal CI/Study - PMA CI/Study - Phase III Study 	 <ul style="list-style-type: none"> - Post-market CI/Study - Investigator Initiated* - PMCF Study - Post-Authorization Study (PAS) - Validation Study 	 <ul style="list-style-type: none"> - 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

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



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



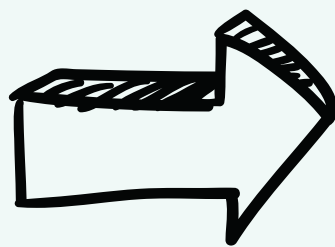
Qualified Subject Database




- 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

Subject Survey Studies

URL, QR Code





You are filling out form 1 of 1

User Experience Evaluation

Which LABmed carpX product did you use?
Tick all that apply

☐ LABmed Micro Protector

☐ LABmed Waterproof carpX Care

☐ LABmed Nano Barrier

Please select at least one option

On a scale from 0 to 10, how would you rate the product?
0 = I did not like to use the product, 10 = I was very satisfied with using the product

0

10

Please answer this question

German Surveys


















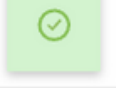
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Search

+ NEW SUBJECT

+ RE-ENROLL SUBJECTS

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Subject Id	Actions	Q
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 002		
 002		
 003		
 004		
 002		

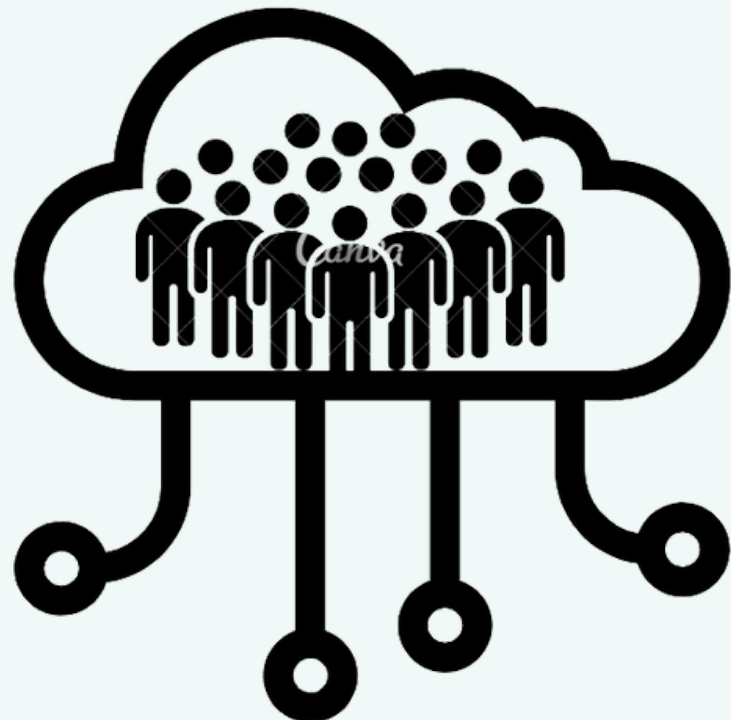
Physician Survey/Case Studies

Public Survey Clinician Database

Broad Clinician Population



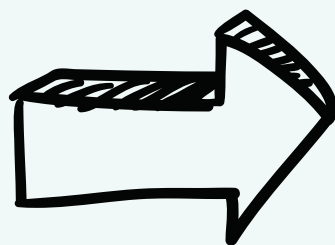
Quallified Clinician Database




- 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)

Physician Survey/Case Studies

URL, QR Code





Access questionnaire(s) for SMART-TRIAL Case Study example

To proceed to your questionnaires, please enter the four digit code you have received via SMS or email.

Code *

Please enter the code you received via email or sms

SUBMIT

RESEND CODE

Case Information

Select clinical application

Possibility 2

Please specify the type of product used

- ☒ Product 1A
- ☐ Product 2A
- ☐ Product 3

Greenlight Guru Clinical Cases > Site Overview

▶ COLLECTING DATA

HELP

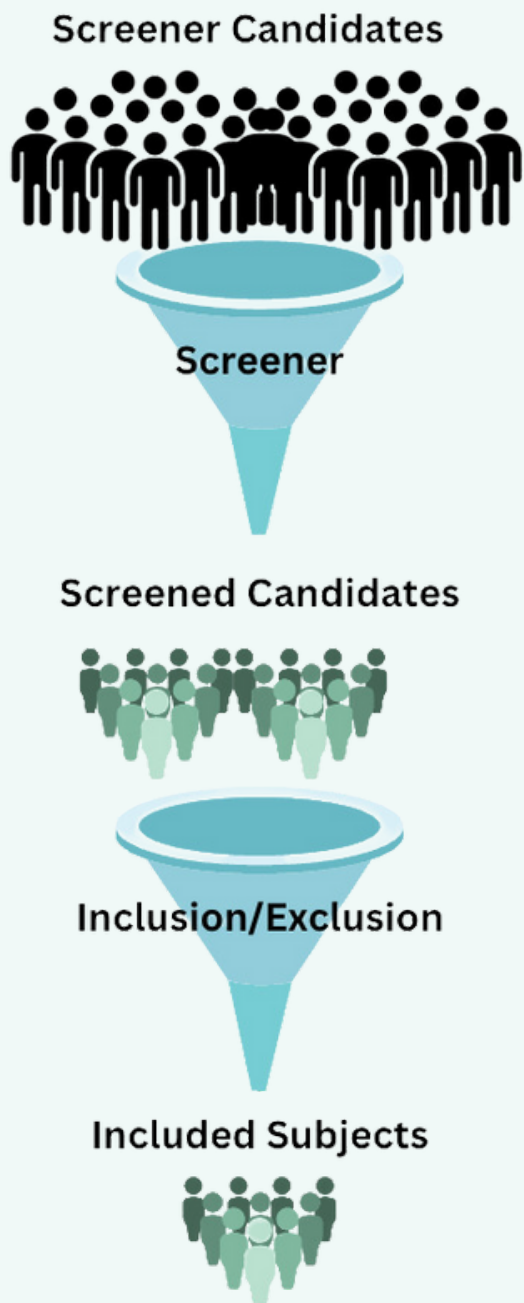
99 NOTIFICATIONS

CHRIS

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✓ olena.kutova@greenlight.guru	Kutova	005	⋮	✓
✓ olena.kutova@greenlight.guru	Kutova	005	⋮	✓
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✓ joningib@gmail.com	Doe	002	⋮	✓
✓ joningib@gmail.com	Doe	002	⋮	✓

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

PMCF Studies, Registries, ITs

greenlight guru

Official Demo 2.0 - eCRF > Sites Overview

COLLECTING DATA

HELP

99 NOTIFICATIONS

CHRIS

Search

28

Total Study Subjects

Today

0

Forms answered

All

3

Completed Subjects

+ NEW SITE

Search

Site Name	Subjects	Ongoing	Completed	Actions
London	26	18	3	<div><div></div><div></div><div></div><div></div></div>
Copenhagen	1	1	0	<div><div></div><div></div><div></div><div></div></div>
Indianapolis	1	1	0	<div><div></div><div></div><div></div><div></div></div>

Page:

1

Rows per page:

25

1 - 3 of 3

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London

Activated Incomplete Expired Completed Cancelled Excluded Missing Data

+ NEW SUBJECT

+ RE-ENROLL SUBJECTS

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PMCF Activities

- General PMCF Activities

- ➔ Literature screening, survey feedback

- Specific PMCF Activities

- ➔ case reports, IIT, registries, PMCF studies, surveys

Time for

Q&A