

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



100+ years of industry experience

522k podcast listeners

200k+ look to us for the latest in MedTech

#1 blog & podcast in the industry

TRUSTED BY LEADING MEDTECH COMPANIES GLOBALLY

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

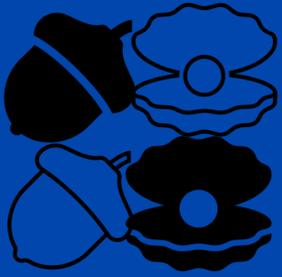


Post Market Clinical Follow-Up according to MDR 2017/745 and MDCG 2020-7 and 2020-8

René Bombien, Chief Medical Officer

2024-03-19

**Add value.
Inspire trust.**



PMCF

Annex XIV Part B



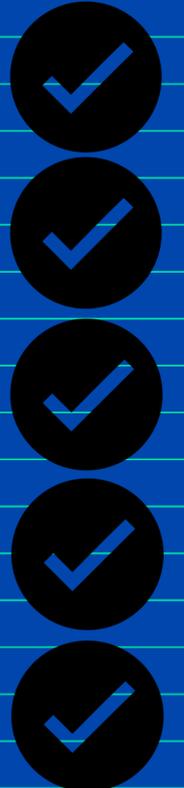
aim of confirming the safety and performance throughout the expected lifetime of the device

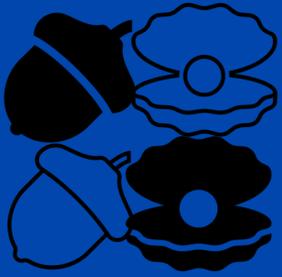
ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence

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

Specific Methods

PMCF Study

Alternatives

Specific Methods

Suitable Registry

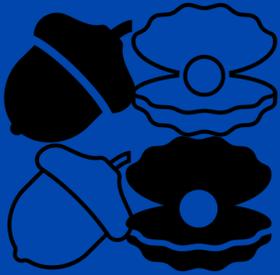
gathering of clinical experience gained

feedback from users

screening of scientific literature

other sources of clinical data

General Methods



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 specification6
 - Section C. Activities related to PMCF: general and specific methods and procedures.....7
 - Section D. Reference to the relevant parts of the technical documentation9
 - 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 specification5
 - Section C. Activities undertaken related to PMCF: results7
 - Section D. Evaluation of clinical data relating to equivalent or similar devices7
 - Section E. Impact of the results on the technical documentation7
 - Section F. Reference to any common specification(s), harmonized standard(s) or guidance document(s) applied.....9
 - Section G. Conclusions9

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

<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
Cardiac Surgeon
Chief Medical Officer
TÜV SÜD Denmark Medical Health Services
E-Mail: Rene.Bombien@tuvsud.com
Website: www.tuvsud.dk

Follow us on:



tuvsud.com
info@tuvsud.com

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

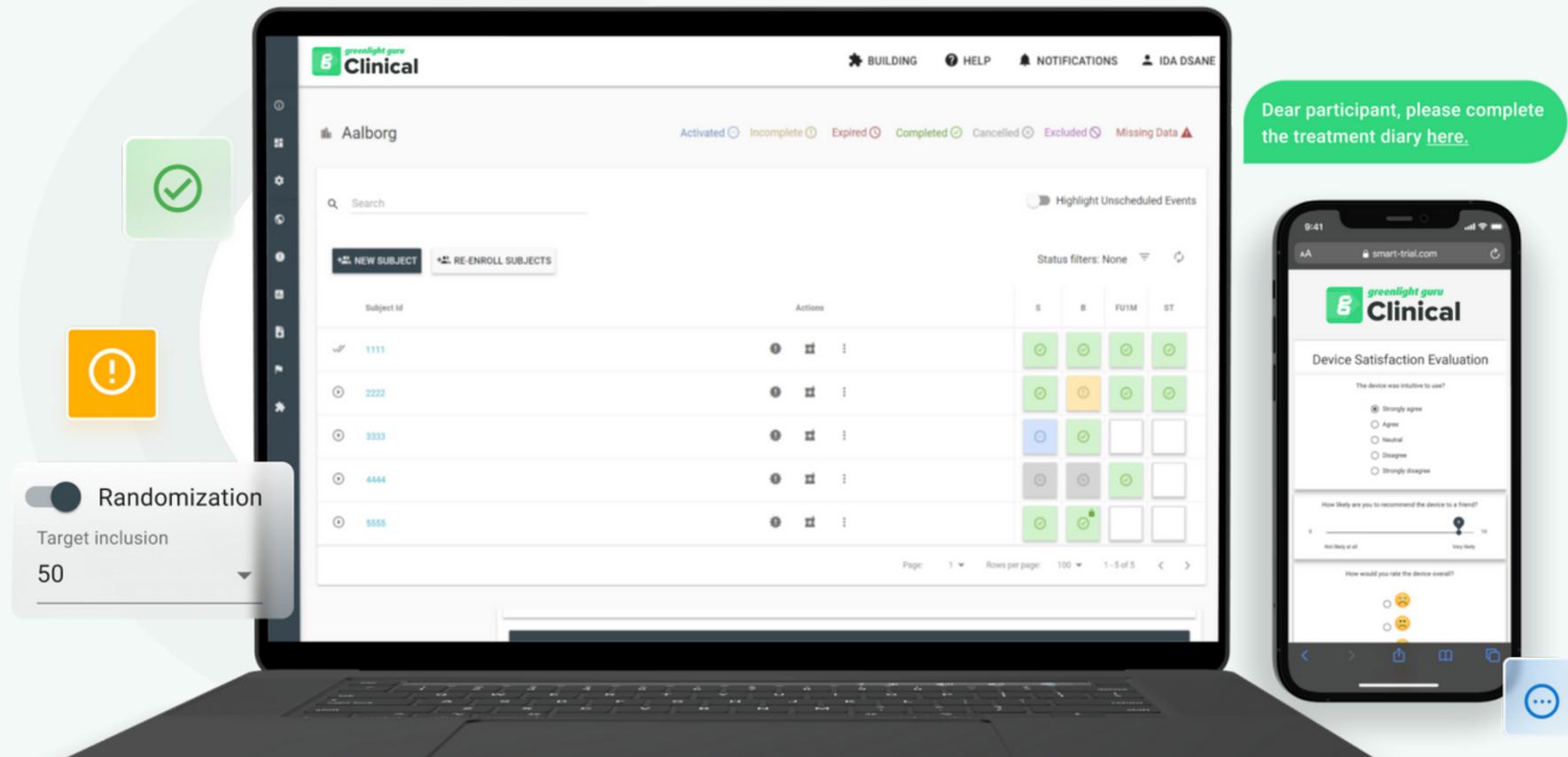
	PRE-MARKET			POST-MARKET	
Clinical Development Stage	Pre-Clinical	Pilot	Pivotal	Post-Market Surveillance (PMS)	
Type	Exploratory	Exploratory & Confirmatory	Confirmatory		Observational
Descriptors	 <ul style="list-style-type: none"> - In-Vitro - In-Vivo - Bench-test 	  <ul style="list-style-type: none"> - 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**



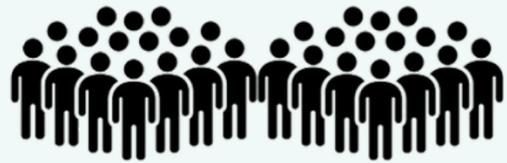
A single, compliant platform for collection and management of all clinical evidence, safety, and performance data.

Learn more here: www.greenlight.guru/clinical

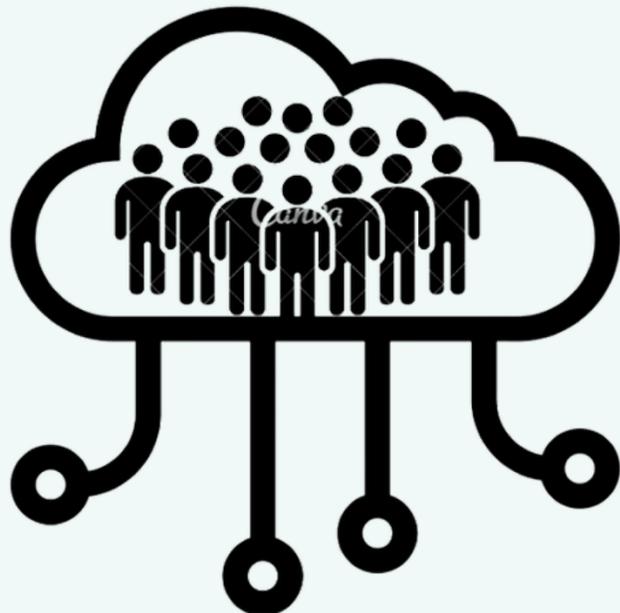
Subject Survey Studies

Public Survey Subject Database

Broad Subject Population



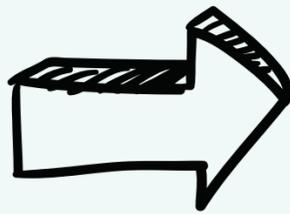
Qualified Subject Database



- 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

Activated Incomplete Expired Completed Cancelled Excluded Missing Data

Search

[+2 NEW SUBJECT](#) [+2 RE-ENROLL SUBJECTS](#) Status filters: None Display Filters

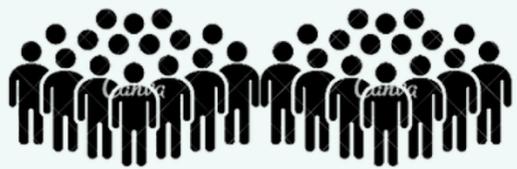
Subject Id	Actions	Q
001	⋮	
002	⋮	
002	⋮	
003	⋮	
004	⋮	
002	⋮	

Physician Survey/Case Studies

Public Survey

Clinician Database

Broad Clinician Population



Survey/questionnaire

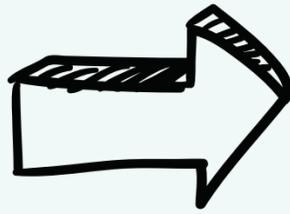
Qualified Clinician Database



- 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




COMPANY LOGO

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

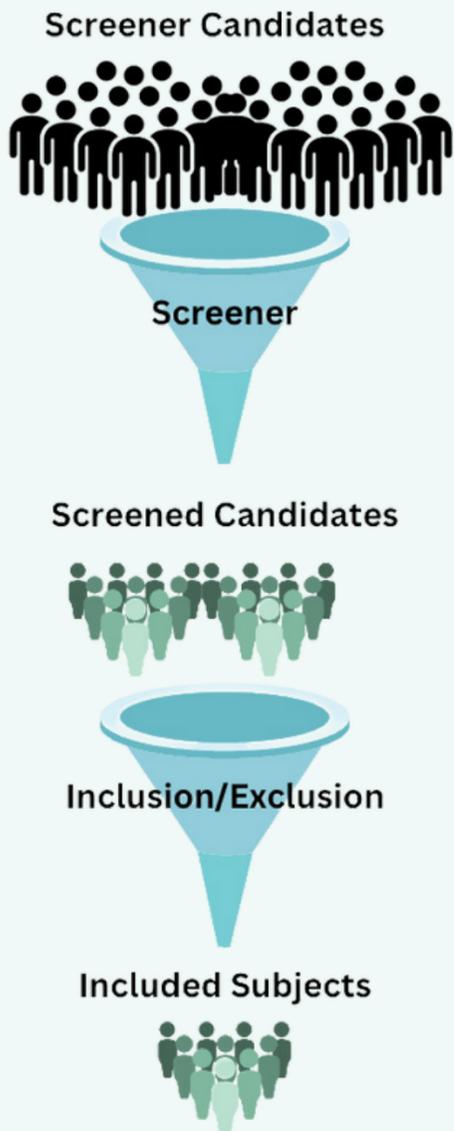
Product 3

Greenlight Guru Clinical Cases > Site Overview ▶ COLLECTING DATA 🔍 HELP 🔔 NOTIFICATIONS 👤 CHRIS

E-mail ▾	Name	Subject Id	Actions	Q
✓ olena.kutova@greenlight.guru	Kutova	005	⋮	✓
✓ olena.kutova@greenlight.guru	Kutova	005	⋮	✓
✓ olena.kutova@greenlight.guru	Kutova	005	⋮	✓
✓ olena.kutova@greenlight.guru	Kutova	005	⋮	✓
⌂ olena.kutova@greenlight.guru	Kutova	005	⋮	⌚
⌂ kimberley.lau@greenlight.guru	Lau	014	⋮	⌚
✓ joningib@gmail.com	Doe	002	⋮	✓
✓ 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 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	
Copenhagen	1	1	0	
Indianapolis	1	1	0	

Page: 1 Rows per page: 25 1 - 3 of 3

London Activated Incomplete Expired Completed Cancelled Excluded Missing Data

Search

+ NEW SUBJECT + RE-ENROLL SUBJECTS Status filters: None Display Filters

Subject Id	Actions	B	V2	V3	FV
002 2023-10-30 08:06 by Kimberley Lau					
003 2022-08-23 14:27 by Chris Rush					
004 2024-02-14 07:46 by Kimberley Lau					
005					
006					
007					
009					
010					
011					

PMCF Activities

- General PMCF Activities

 - ➔ Literature screening, survey feedback

- Specific PMCF Activities

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

Time for

Q&A