element

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Holistic Approach to Clinical Evaluations

Learn about sufficient clinical evidence within the context of a clinical development plan and when a clinical investigation is necessary

Chems Hachani

Burhan Mehmedi

HISTORY OF THE COMPANY

Featured in Forbes · LSI LIFE SCIENCE INTELLIGENCE · bsi.

Oct 2020 — Creation of the company

Oct 2022 — ECLEVAR MEDTECH

>1M CA

Oct 2023 — PUBLIC RELEASE

MILO
MEDICAL INTERFACE LIAISON OFFICER

Dec 2023 — ISO Certificate

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE
MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR ET DE LA RECHERCHE

JEI
Jeune Entreprise Innovante

CRÉDIT D'IMPÔT RECHERCHE
AGRÉMENT CIR

International Organization for Standardization
ISO
13485
Quality Management System

Information Security Management
ISO 27001
Certified

Leadershi

Chems HACHANI: With almost **10 years'** experience across business development, marketing and clinical development, Chems generates a high-performance culture that attracts top talent and partners. His additional core specialties include RWE clinical trials, market access and medical writing.

Edmund White: Over **20 years** of progressive global commercial leadership experience in MedTech, Digital Health & Clinical Research Organizations. Understanding the prevailing MedTech challenges. Navigating the complexities of MDR/IVDR. Enabling innovative & cost-effective solutions to MedTech & Diagnostics at scale & speed so patients can ultimately receive the best life-saving therapies.

Burhan Mehmedi: With more than **15 years** in the medical industry in a variety of positions; clinical, regulatory. He has spent the last 11 years working in medical device area. He started off in a Clinical Project Manager position for Phase I to III Pharma studies, device studies, inpatient studies, infusion and drug reconstitution studies. Diabetes, Cardiology, Asthma, Allergy, Immunology.

Leadershi

Idil Gurkan Ozturk: Global Clinical Project Delivery Manager.

20 years experienced Line Management and Clinical Project Delivery Management with a demonstrated history of working in the pharmaceuticals industry at both Pharmaceutical Company and CRO

Art Pilmeyer, Internal referent Electrophysiology

Arne Heissel, PhD, Head of Reimbursement EMEA

20 years experienced in reimbursement over 36 countries.

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Medical team

DR. JEAN MARC DERSOT

MEDICAL EXPERT
REFERENT DENTAL SURGERY

PR. YANN GOUEFFIC

MEDICAL EXPERT
REFERENT VASCULAR SURGEON

PR. LUC TEOT

MEDICAL EXPERT
REFERENT WOUND REPAIR & REGENERATION

DR. JOACHIM ALEXANDRE

MEDICAL EXPERT
REFERENT CARDIOLOGY

PR. STEFAN DROUPY

Professor of Urology in Montpellier University, Chairman of the urology and andrology department. in CHU de Nimes.

DR. YOUSSEF EL DSOUKI

MEDICAL EXPERT
REFERENT PERFUSION & CATHETER

PROF. RAPHAËL COSCAS

APHP

DR. NASR BAHAA

CHU Brest

PROF. MAUREL DESANLIS BLANDINE

CHU Nantes

DR. MARKO LUKIC

Referent for Ophtalmology

DR. ADEL ABOU-MRAD

Referent for digestive surgery

SERDAR GUNAYDIN, MD, PHD

Clinical Professor, Department of Cardiovascular Surgery

Clinical Development Plan (CPD)

"To plan, continuously conduct and document a clinical evaluation, manufacturers shall establish and update a clinical evaluation plan, which should include (amongst other criteria)

a) a CDP indicating progression from exploratory investigations

- Pivotal clinical investigations
- a PMCF as referred to in Part B of Annex XIV of MDR with an indication of milestones and a description of potential acceptance criteria.

b) generate, through properly designed clinical investigations in accordance with the clinical development plan, any new or additional clinical data necessary to address outstanding issues.

The relationship between CDP and CEP

The CEP outlines the clinical strategy that the manufacturer shall follow to justify the safety and performance of their device in accordance with the General Safety and Performance Requirements (GSPR) of the MDR

The CDP is a subset of the CEP focusing specifically on the clinical investigations for the given device that:

- Have already been conducted, preferably with a full clinical investigation report available
- Are being conducted with a full clinical investigation protocol available, or
- Are planned in the future – these could include pilot, pivotal, or PMCF studies. Preferably, the synopsis of this study should be included in the CDP in this case

CLINICAL CLAIMS

All Clinical Claims are required to be quantified

Safety Claims

Re-occlusion of the artery	< 6.5%
Amputation	≤7%

CLINICAL CLAIMS

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Performance Claims

Visibility (User needs to accurately monitor position/orientation the needle during use)

Trackability to the anatomical site (User needs to access the region of interest through puncture of soft tissues and organs)

Aspiration and/or injection of fluids (User needs to perform aspiration / injection of fluids and introduce guidewires through the needle cannula)

Compatibility with other devices (User needs a needle compatible with interfacing devices (e.g. guidewires, syringes)

None of them is Clinical Performance Claim

CLINICAL CLAIMS

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Performance Claims

Removal of fresh, soft emboli from the peripheral arterial system	Procedural success >95% Patient satisfaction surway

Lifetime of the device

Survival rate	Kaplan Mayer Score >95% at 5 years

CLINICAL CLAIMS

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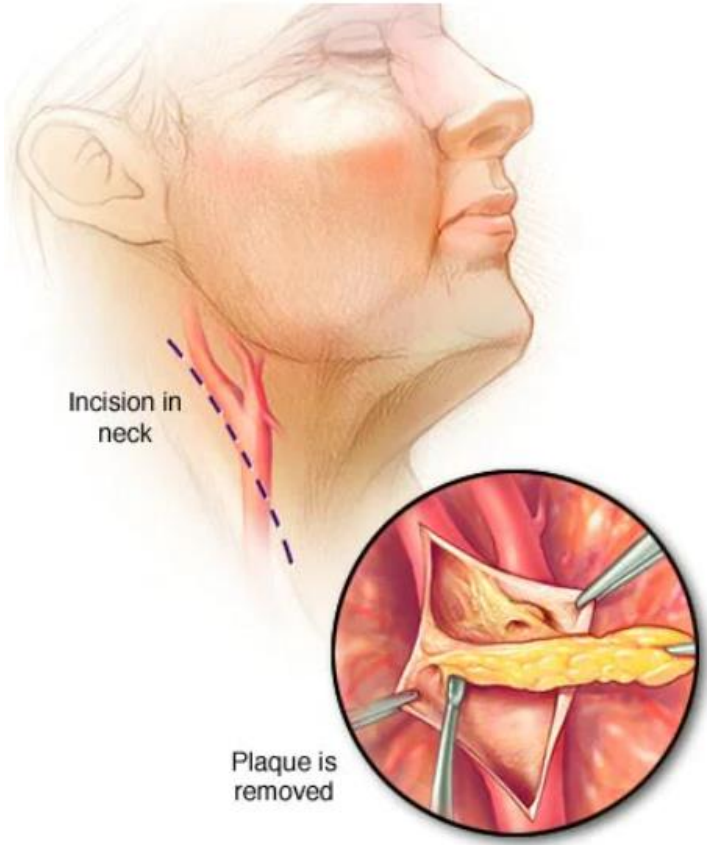
Clinical Benefits

rapid removal of emboli and thrombi from the arterial system	→	Quality of Life Score Mortality rate <2% at 30 days Patient Satisfaction Score
reduce the recurrent embolism as the most important cause of reoperation and amputation	→	Reduction of pain Mortality rate <2% at 30 days Patient Satisfaction Score

Example of NB feedback

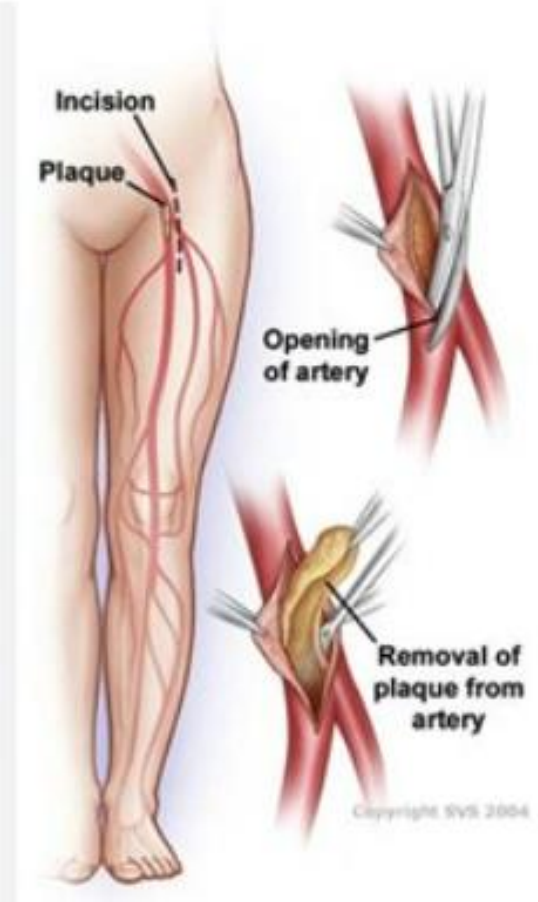
Medical device is indicated in **vascular angioplasty** and **especially for carotid endarterectomy**.



https://newsnetwork.mayoclinic.org/discussion/mayo-clinic-q-and-a-new-treatment-to-open-blocked-carotid-artery/

Device is on the market since 20 yr

> 3 yr of follow-up



https://vascularsurgery.ucsf.edu/conditions--procedures/lower-extremity-bypass-surgery.aspx

Clinical Strategy

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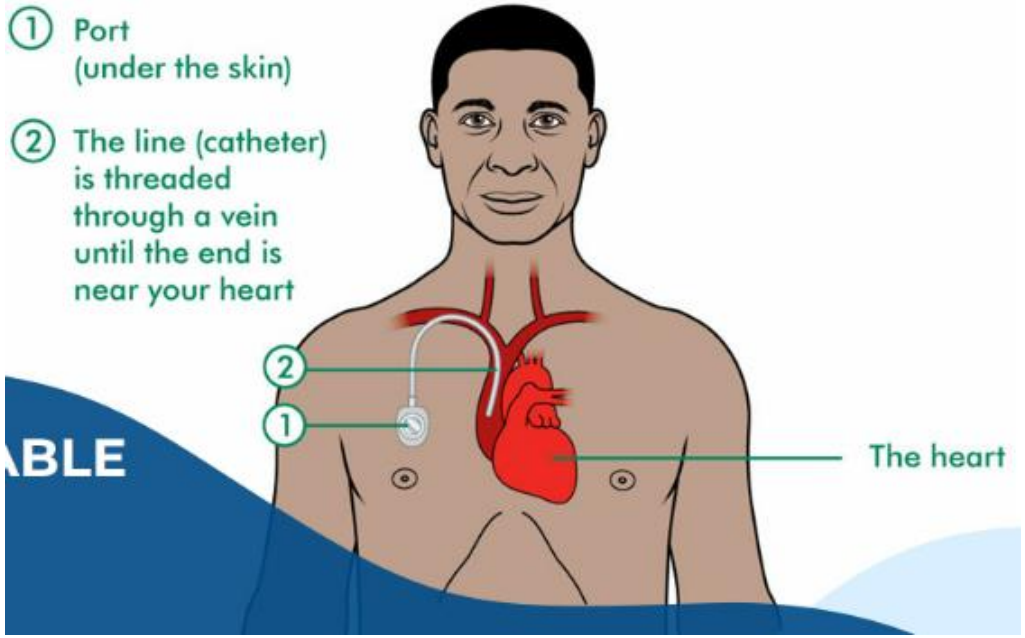
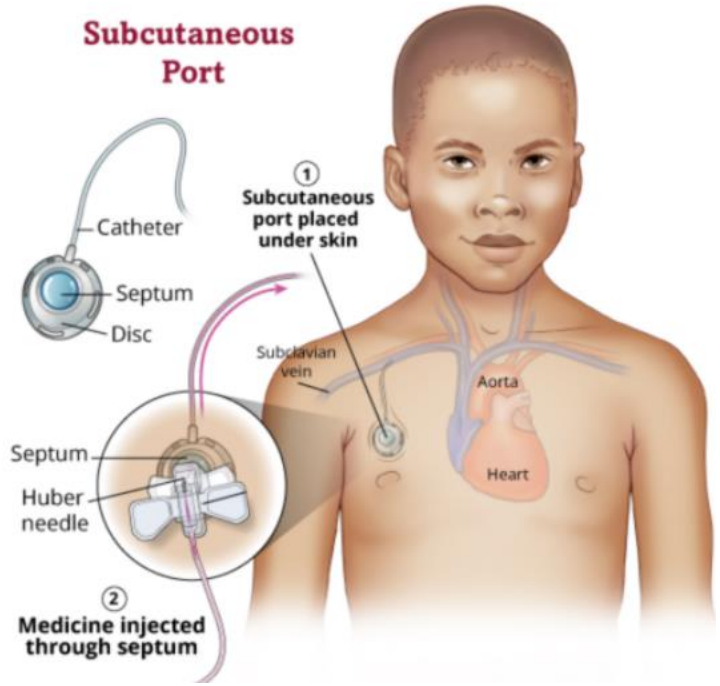
- Clinical Claims
- Clinical Endpoints
- Class of the device (level of evidence)
- History of collected clinical data (clinical developement plan)

Differents variants but not the same clinical effect

Chemotherapy
Antibiotics
Blood sampling
Parenteral nutrition

Adults and Pediatrics





Implantable catheter ports 2000, 3000, 4000 series

Post-Market Clinical Follow-up (PMCF)

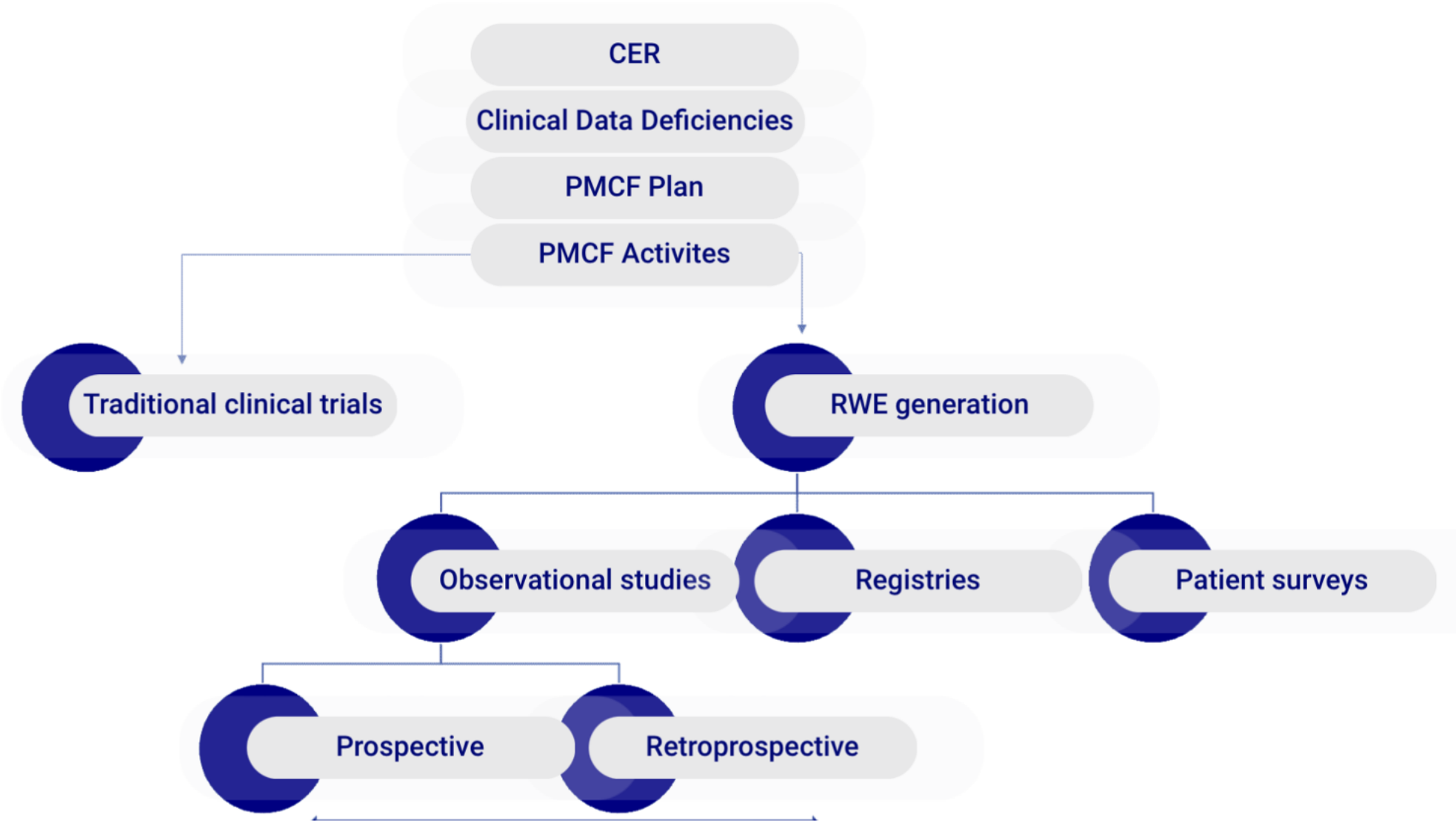
Post-Market Clinical Follow-up (PMCF) is one part of the overall PMS, and the EU MDR defines PMCF as **a continuous process** that updates the clinical evaluation referred to in Article 61 Clinical Evaluation and Annex XIV Part A Clinical Evaluation.

PMCF is a proactive collection with the aim of confirming the **safety and performance** of the device throughout its **expected lifetime**.

When PMCF study is required

- The product is **new/ employs novel technology**, for which there isn't substantial clinical evidence demonstrating safety and performance
- The product is **high risk** according to the risk classification rules of EU MDR, or the risk classification of the product has changed under the EU MDR
- The available clinical evidence is **outdated**, or has data gaps in relation to the intended use or indications for use
- The medical device has undergone **significant changes** since initial placement on the market, such as new or changed intended use or indications for use
- **New emergent risks** identified via customer complaints, adverse event reporting etc.

PMCF activities



What is RWD/RWE?

Real-World Data:

Routinely collected data relating to patient health status or the delivery of health care from a variety of sources other than traditional clinical trials

- Electronic health records (EHRs) / medical records
- Medical claims and billing data
- Product, disease and population-based registries
- Patient-generated data
- Health status via mobile devices (Wearables)
- Social Media Data
- Patient Support Programs

Real-World Evidence:

- Information derived from analysis of real-world data
- Insights regarding the heterogeneous patient population outside of the clinical trial setting
- Identifying the gaps between research and everyday practice

Clinical investigations

•Both, pre-market- and PMCF clinical investigations are more likely to have **restrictive eligibility** criteria designed to ensure that the participants have the disease of interest or have specific patient characteristics.

•Real World Data and the systematic analysis without the above-mentioned limitations, and in accordance with ISO 14155:2020, can be collected well and generate RWE by conducting observational clinical investigation: a registry or a post-market clinical investigation, non-interventional. Such methodologies can collect data prospectively or retrospectively; it depends on the design of the clinical investigation.

Q&A

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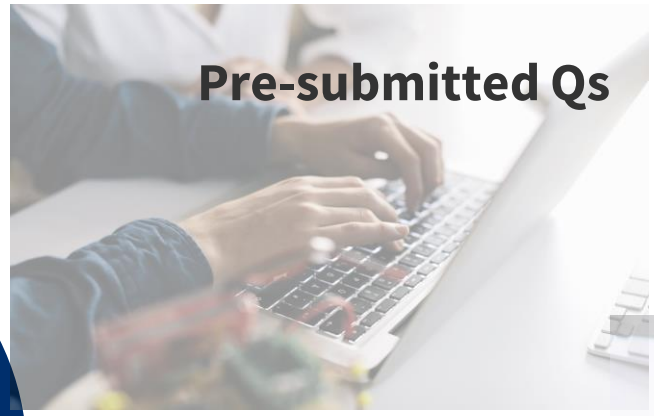

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