



**HaMaDa**  
Regulatory • Clinical • Quality Affairs  
for the MedTech Industry

# PMCF Strategy for Successful Clinical Evidence

*MDI – 19 Mar 2024*

# HaMaDa Background



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CMO RAQA Division



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Head of CRO



Daniele Perl-Treves PhD.  
Head of Clinical Writing Team





# HaMaDa

## Your Product Lifecycle A-Z



### R&D

RA Requirements | Risk Management  
Literature review | Design Phase QA |  
Preparations for V&V | Pre-Clinical &  
Clinical Studies | DHF

Develop ● product

New ● product



### IDEA

Regulatory planning & strategy |  
Clinical Strategy | Budgeting

### Market Approval / Release

Submissions to Reg. Authorities |  
Ongoing RA | Compliance Support |  
Internal & External Audits | Articles



Hooray ● Certification

Almost ● There



### Engineering & TTP

Regulatory Support | QMS  
Establishment & Certification |  
Clinical Evaluation | DMR |  
Submission Preparation |  
Clinical Studies

Sales ● Post Market FU

### Sales & Post Market



PMS | PMCF | Continuous  
Regulatory maintenance |  
QMS Maintenance |  
Publications | Post Market  
Studies

# PMCF Strategy for Successful Clinical Evidence

## Dr. Naida Gurshumov (PhD)

- Clinical Research Consultant & Medical Writer
  - PhD in Medical Sciences, Tel Aviv Univ.
  - 25 years experience in clinical research industry
  - Clinical projects in all major therapeutic areas
  - CROs, biotech and pharma experience
  - Development of clinical strategies, including PMCF



## Key Points

- I. Introduction to PMCF
- II. Challenges in PMCF for Biotech and Medical Device Companies
- III. Strategies for Successful PMCF Implementation
- IV. Case Studies and Best Practices
- V. Conclusions



## Post Marketing Clinical Follow Up (PMCF)

- PMCF is a **process** of collecting clinical data on the safety and performance of medical devices or biotech products after they have been placed on the market.



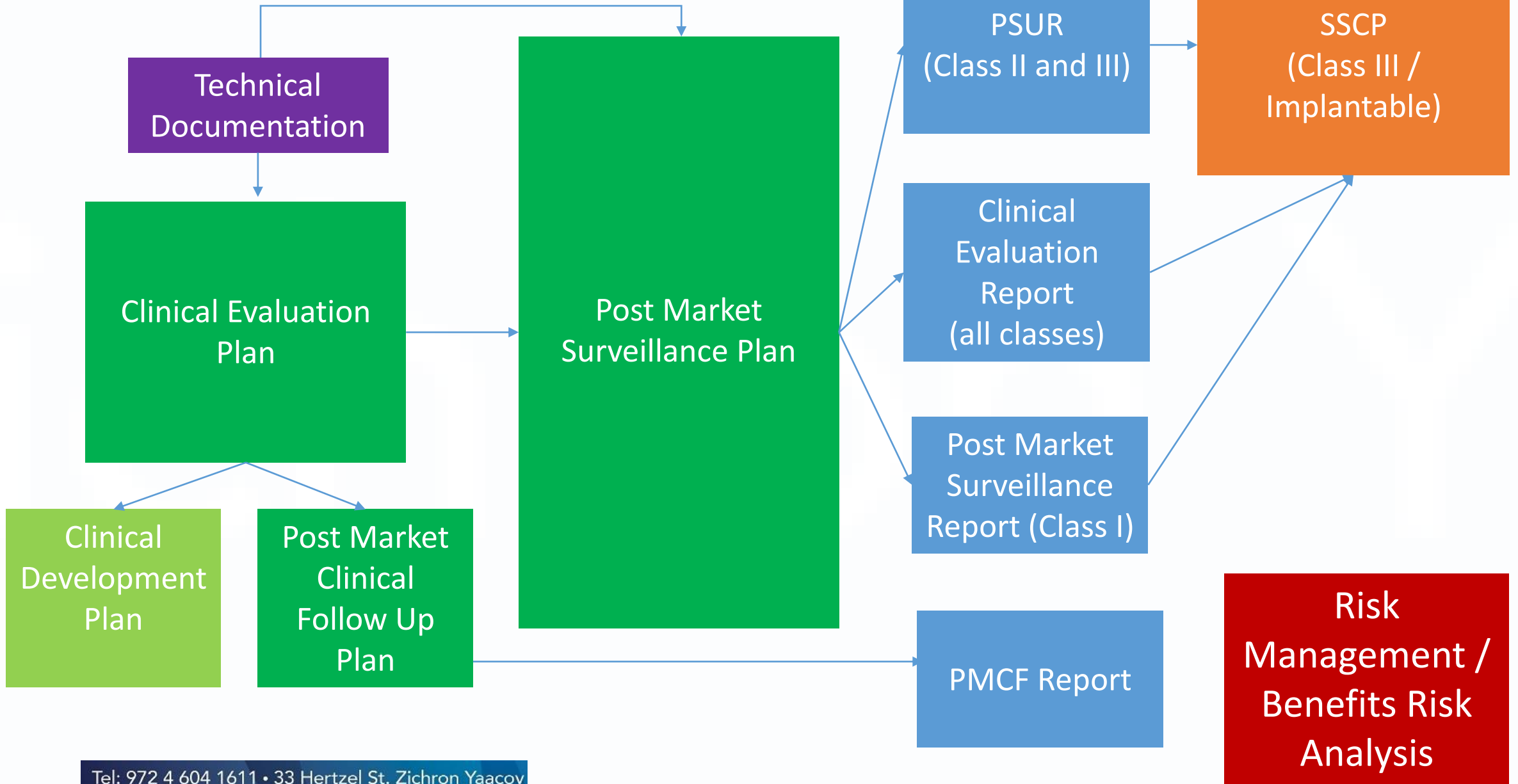
# Importance of Post Market Clinical Evidence

1. Ensure continuous evaluation of a product's benefits and risks in clinical practice

2. Critically important for:

- company itself
- physicians
- investors
- distributors
- NBs
- stakeholders
- patients





# Basic Regulatory Requirements

## EU MDR 2017/745

- Article 32 (SSCP), Article 83-86 (PMS), Article 87-92 (Vigilance), Article III (PMS), Article XIV (CER/PMCF)

## ISO/TR 20416:2020

- Medical Devices – Post Marketing Surveillance for Manufacturers

## US FDA 21 CFR 822

- Post Marketing Surveillance

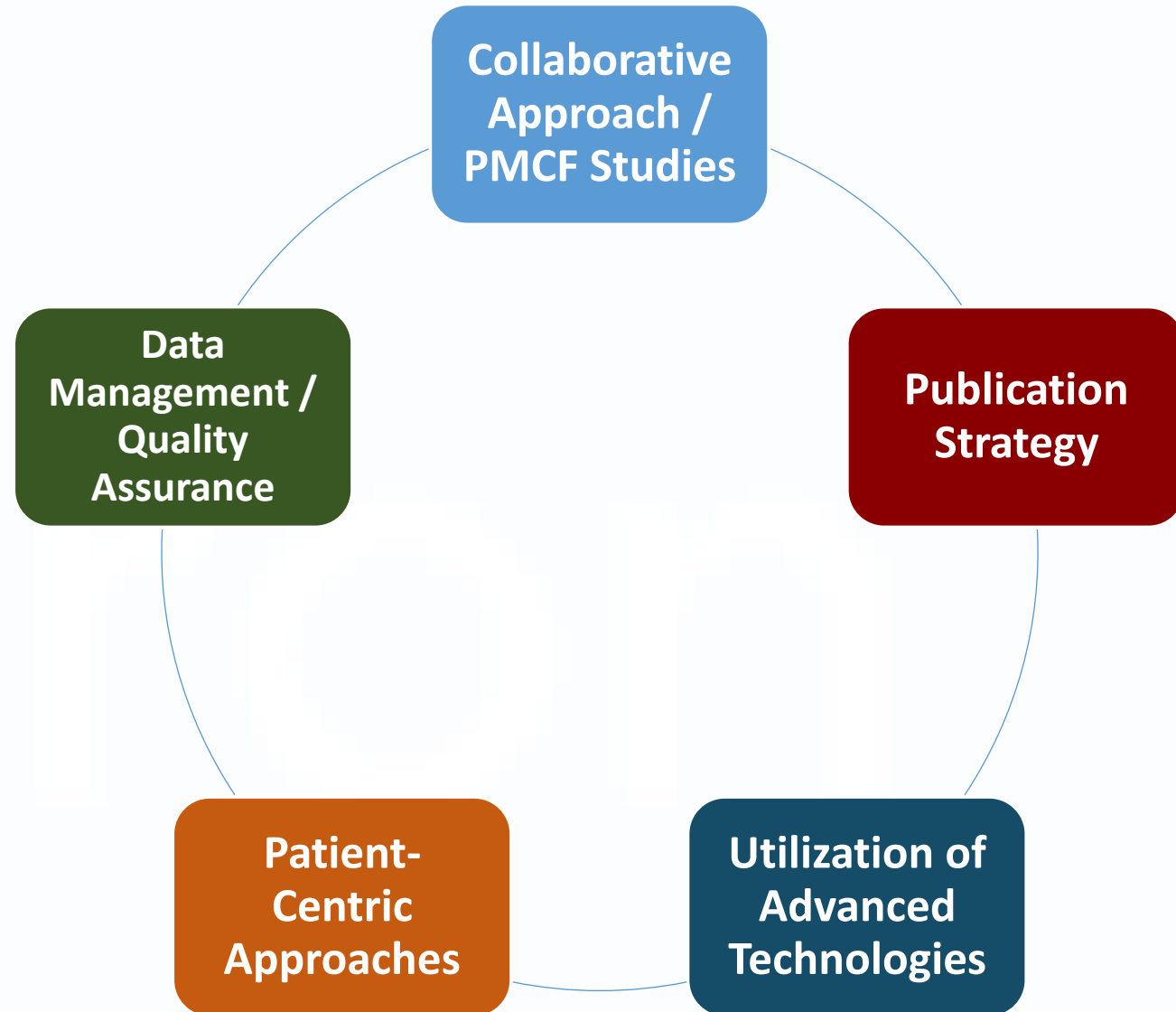
## World Health Organization

- Guidance for Post Market Surveillance and Market Surveillance of Medical Devices, including in Vitro Diagnostics

# Challenges in PMCF for Biotech and Medical Device Companies

- Data Accessibility and Quality
- Regulatory Compliance and Patient Privacy
- Longitudinal Data Collection
- Data Analysis and Interpretation
- Resource Constraints and Budget Management

# Strategies for Successful PMCF Implementation



# Strategies for Successful PMCF Implementation

## 1. Collaborative Approach / PMCF studies - collaborative approach to PMCF involves engagement with:

- stakeholders
- healthcare providers
- patients
- regulators
- industry partners



# Strategies for Successful PMCF Implementation

**2. Publication Strategy** - provide guidance on developing a clear clinical development and publication strategy, including

- consideration of all available clinical data
- choice of authors and journals
- post-publishing marketing strategy



# Strategies for Successful PMCF Implementation

## 3. Data Management and Quality Assurance - offer strategies for implementing

- standardized data collection protocols
- validating data quality
- ensuring robust data management
- ensuring quality assurance processes





# Strategies for Successful PMCF Implementation

## 4. Patient-Centric Approaches - emphasize the importance of patient-centricity in PMCF, including

- obtaining informed consent (or waiver)
- protecting patient privacy
- implementing patient engagement and patient retention strategies



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# Strategies for Successful PMCF Implementation

## 5. Utilization of Advanced Technologies - highlight the role of advanced technologies such as

- advanced data collection and analysis
- digital health tools
- remote monitoring



## Case Study: Cardiovascular Device

- **Background:** Implantable device for treating heart rhythm disorders.
- **PMCF Strategy:**
  - use of prospective and retrospective patient registries
  - collaboration with healthcare providers
  - leveraging electronic health records for data collection.
- **Outcome:** Through ongoing PMCF activities:
  - previously unknown safety issues were identified
  - device programming algorithms were optimized
  - valuable insights into patient outcomes were provided.



# Case Study: Laser Tattoo Removal Device

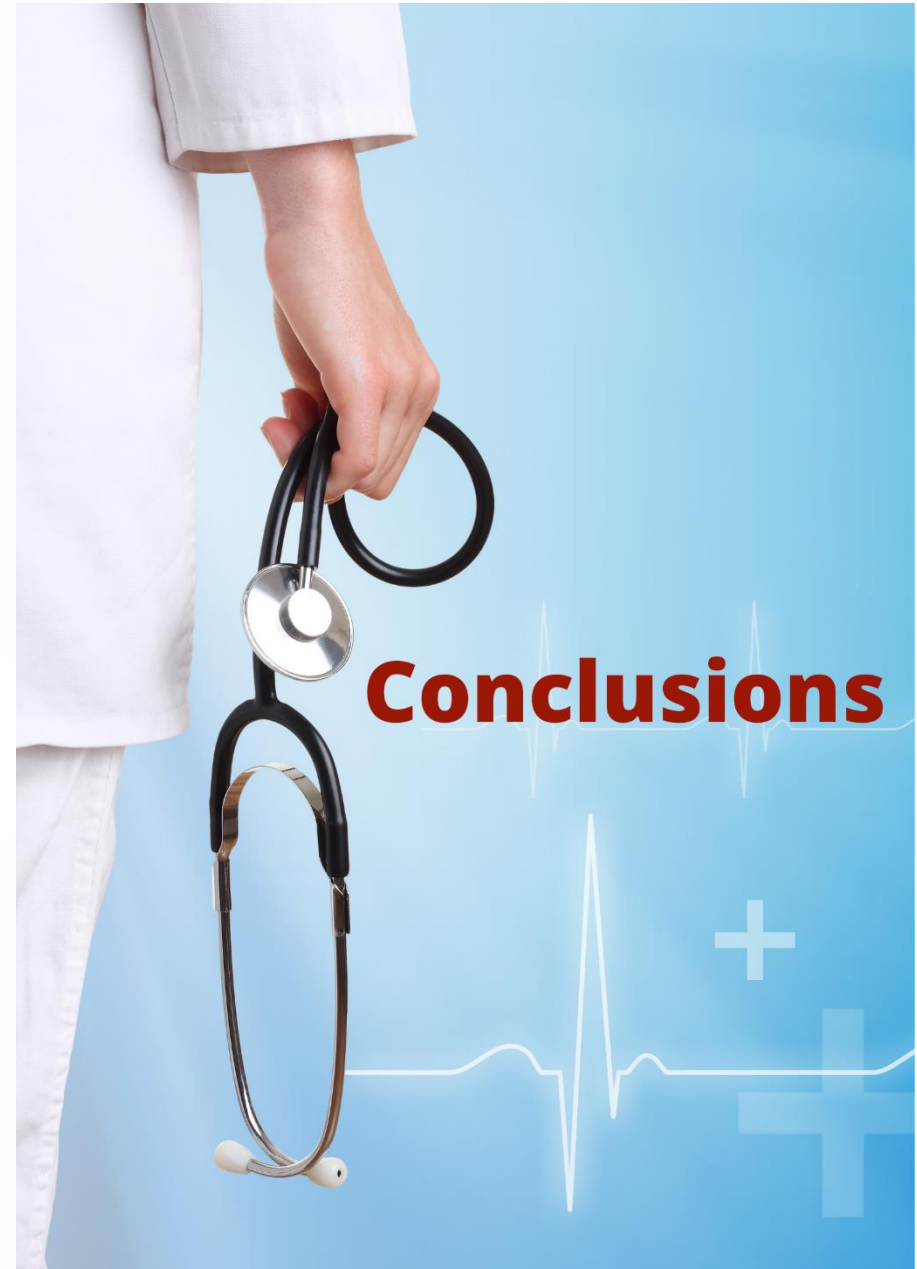
- **Background:** laser treatment device for non-invasive tattoo removal.
- **PMCF Strategy:**
  - prospective registry with tattoo removal clinics
  - multi-center observational study
  - patients follow-up and surveys
  - education to practitioners for proper device usage
- **Outcome:**
  - valuable insights into long-term efficacy, safety, and patient satisfaction.
  - optimization of treatment protocols
  - enhanced market acceptance of the technology.



# Best Practices

- Establish Clear Objectives and Endpoints
- Engage Stakeholders
  - ✓ incl. patients, healthcare providers, regulators, industry partners, etc
- Utilize Diverse Data Sources
- Implement Robust Data Management
- Adopt Innovative Technologies
- Monitor and Adapt

- **Strategic Approach is Essential**
- **Interdisciplinary Collaboration is a Key**
- **Continuous Adaptation is Critical**



## PMCF is a JOURNEY!

**“IF YOU CAN’T FLY, THEN RUN, IF YOU CAN’T RUN, THEN  
WALK, IF YOU CAN’T WALK, THEN CRAWL,  
BUT BY ALL MEANS KEEP MOVING.”**

*/MARTIN LUTHER KING/*

*Good Luck!*  


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