Aktualisierung der klinischen Bewertung
Effiziente Umsetzung der MDCG Leitlinien 2020-7 / 2020-8

Dagmar Glashoff-Dedek & Sarah Panten (avasis)
1847
A small garage startup in Berlin, Germany

Employees: 10
Start-up capital: 6,842 thalers
1st year revenue: 3,420 thalers
Software company in the world

**Top 10**

<table>
<thead>
<tr>
<th>R&amp;D Expenditures</th>
<th>List of top rated companies</th>
<th>Software developers</th>
<th>Siemens Digital Industries Software revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>€5.6bn</td>
<td>#1 Fortune</td>
<td>24,500+</td>
<td>€3.4bn</td>
</tr>
<tr>
<td>Industrial software</td>
<td>Offerings 250+</td>
<td>Including digital services and industrial applications</td>
<td>Fortune 500 industrial customers 92%</td>
</tr>
</tbody>
</table>
Sarah Panten

- Business Development Medical Device Solutions
- Senior Consultant Medical Devices
- Polarion Implementation, QM/RA Support
- Product Manager Medical Devices, Deputy QMR
- Trainer Medical Device Law, ISO 13485, Clinical Evaluation, Post-market Surveillance
- QM/RA Consultant
- Lead of Clinical Evaluation Team
- International Product Manager Urology
- Dipl.-Ing (FH) Medizintechnik
Added Value:
Long-term partnership & continuity
Consistent solutions for a platform from one source
Smart Expert Partner of Siemens - future-proof partnership
Competent, dedicated consultants and software specialists from avasis
We know the challenges of the medical device industry and accompany tool implementation and validation

Switzerland, Germany, Austria

Siemens Partner
- Polarion
- Teamcenter
- NX
- QMS

Services
- Beratung
- Implementierung
- Schulung

Own Products
- avaRisk
- avaUsability
- avaClinical
- avaMedbase

Team
1. Aktualisierung KB - MDCG Anforderungen
   Inhalte der MDCG Leitlinien 2020-7/2020-8

2. Polarion Templates
   Effiziente Erstellung von PMCF Plan
   und PMCF Evaluation Report

3. Schnittstellen zwischen Prozessen
   Verknüpfung und Konsistenz von Informationen
   in der klinischen Bewertung, PMCF und Risiko
   Management

4. Question & Answer Session
1. Update klinische Bewertung

Übersicht der Anforderungen aus den MDCG Leitlinien 2020-7 und 2020-8
Demonstrate sufficient evidence for

1. Clinical safety
2. Clinical performance
3. Clinical Benefit
4. Evidence for marketing claims

Conclusion:
• Benefit > Risk?
• Open clinical questions?
• Required PMCF activities?

Based on clinical data (Scientific literature, Clinical Studies, Post-market Surveillance)
Goal of Post-market Clinical Follow-up (PMCF)

- Continuous process that updates the Clinical Evaluation for CE marked devices
- PMCF is an element of the post-market surveillance (PMS) system
- Goals:
  1. Confirm clinical safety and performance throughout lifetime
  2. Ensure continued acceptability of identified risks
  3. Detect emerging risks
Process for Update of Clinical Evaluation (PMCF)

Clinical Evaluation Plan (CEP)
- Identification of Data
- Appraisal of Data
- Analysis of Data

Clinical Evaluation Report (CER)

PMCF Plan

Post-market Clinical Follow-up (PMCF)
= Continuous update of clinical evaluation with new clinical data as part of post-market surveillance activities
Process for Update of Clinical Evaluation (PMCF)

- Clinical Evaluation Plan (CEP)
  - Identification of Data
  - Appraisal of Data
  - Analysis of Data
  - Clinical Evaluation Report (CER)

- PMCF Plan
  - Identification of Data
  - Appraisal of Data
  - Analysis of Data
  - PMCF Evaluation Report

Post-market Clinical Follow-up (PMCF)

= Continuous update of clinical evaluation with new clinical data as part of post-market surveillance activities
Process for Update of Clinical Evaluation (PMCF)

Post-market Clinical Follow-up (PMCF)
= Continuous update of clinical evaluation with new clinical data as part of post-market surveillance activities
Update within the Product Lifecycle

Update until end of Life Cycle!

- CEP
  - collection
  - appraisal
  - analysis

- CER v1
  - collection
  - appraisal
  - analysis

- Updated CER v2
  - collection
  - appraisal
  - analysis

- Updated CER v3
  - collection
  - appraisal
  - analysis

Product Development 2020

CE Mark

2021

Minimum Check Required
European MDCG Guidances

- Guidances for implementation of Medical Device Regulation (MDR) requirements
- For manufacturers and notified bodies
- Goal: harmonized and complete representation of required information
- Legally not binding, but considered as state of the art = application expected

<table>
<thead>
<tr>
<th>Reference</th>
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<th>Publication</th>
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<tr>
<td>MDCG 2020-8</td>
<td>Guidance on PMCF evaluation report template</td>
<td>April 2020</td>
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<tr>
<td>MDCG 2020-7</td>
<td>Guidance on PMCF plan template</td>
<td>April 2020</td>
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<tr>
<td>MDCG 2020-6</td>
<td>Guidance on sufficient clinical evidence for legacy devices</td>
<td>April 2020</td>
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<tr>
<td>MDCG 2020-5</td>
<td>Guidance on clinical evaluation – Equivalence</td>
<td>April 2020</td>
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<tr>
<td>MDCG 2019-9</td>
<td>Summary of safety and clinical performance</td>
<td>August 2019</td>
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# Requirements for PMCF Plan / PMCF Evaluation Report

Example Structures based on MDCG Guidances

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<td>- National authority database review</td>
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<td>3.2</td>
<td>- Literature Review Plan</td>
<td>- Literature Review Results</td>
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<tr>
<td>3.3</td>
<td>- PMCF Study Plan</td>
<td>- PMCF Study Results</td>
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<td>3.4</td>
<td>- … (Plan of other PMCF activities)</td>
<td>- … (Results of other PMCF activities)</td>
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Input for PMCF Plan and Output for PMCF Evaluation Report

**INPUT for PMCF Plan**
- TD (Annex II), chapter xx
- Clinical Evaluation Report (CER)
- Risk File
- TD (Annex II), chapter XX

**PMCF Plan**
- Medical Device Description
- Planned PMCF Activities
- Equivalent/Similar Devices
- Input from CER, Risk File, other TD Parts
- Relevant CS, standards, guidances

**PMCF Evaluation Report**
- Medical Device Description
- Results of PMCF Activities
- Data for Equivalent/Similar Devices
- Output for CER, Risk File, other TD Parts
- Conformity with CS, standards, guidances
- Summary & Conclusion

**OUTPUT from PMCF Report**
- Clinical Evaluation Report (CER)
- Risk File
- TD (Annex II), chapter XX
- PMS Report or PSUR

Minimum Check Required
2. Polarion Templates

Effiziente Erstellung von PMCF Plan und PMCF Evaluation Report

3. Verknüpfung von Prozessen

Konsistenz von Informationen in der klinischen Bewertung, PMCF und dem Risiko Management erreichen
Clinical Evaluation acc. to MDR and MEDDEV 2.7/1
Achieve completeness and consistency with Polarion

1. Digital Clinical Evaluation
   Why Excel and Word are not the best options

2. Clinical Evaluation Plan
   Systematic and efficient planning

3. Literature Review
   Simplified execution and documentation

   Traceability of clinical evidence to single data sets,
   Achieve consistency with risk management
Vielen Dank für die Aufmerksamkeit!

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Portfolio Development Manager
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Fragen?