VDI Technologiezentrum

BEAUFTRAGT VOM

Bundesministerium für Bildung und Forschung

Funding of clinical trials in medical technology

Bundesanzeiger, Juli 2018

Medizintechnische Lösungen in die Patientenversorgung überführen – Klinische Evidenz ohne Verzögerung belegen

Proposals at any time!

Dr. Monika Weinhold, weinhold@vdi.de

Clinical evaluation towards certification

Proof of safety and performance of medical devices and IVD

MDR/IVDR, Art. 61/56: based on sufficient clinical data

https://pixabay.com/de/illustrations/europa-paragraf-recht-europarecht-3083111/

Clinical investigation

Complex regulatory framework (regulations, guidelines, standards)

Risk and quality management

Purpose of funding

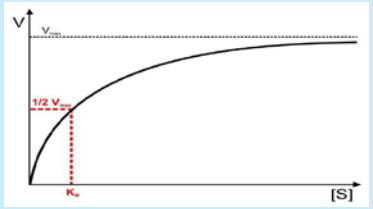
Introduce SME to regulatory framework

Establish clinical evaluation processes

Transfer MedTech-funding to clinical R&D

Ensure early clinical testing and evaluation

Transfer innovative medical technology to medical care



Scope of funding

Modul 1_Qualification: study design

- Establish regulatory expertise
- Prepare clinical trial

Modul 2_Implementation: study performance

- Expand qualification
- Conduct clinical investigation and evaluation

Scope of funding

All medical indications

- Medical class IIa, IIb, III devices
- In vitro diagnostic class B, C, D medical devices

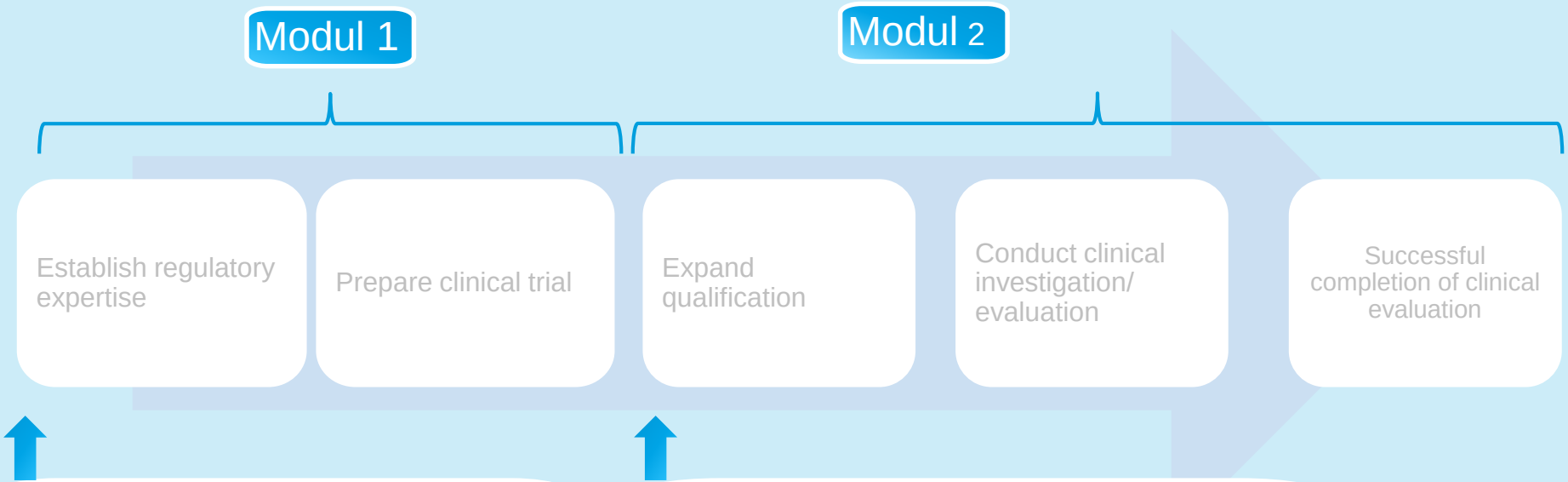
Eligible for funding

- Prospective clinical trials
- Mono-/Multicenter
- Exploratory/confirmatory

Excluded from funding

- Trials for re-certification of CE-products
- Post-Market Surveillance studies

Requirements



Framework for State aid / AGVO

Training aid (FQ 50 % + max. 20 % SME-bonus)

- Costs of qualification measure (personal, material, travel, advisory services)

Innovation aid for SMEs (FQ 50 %)

- Innovation advisory and support services
- Secondment of highly qualified personnel
- Costs for obtaining, validating and defending patents

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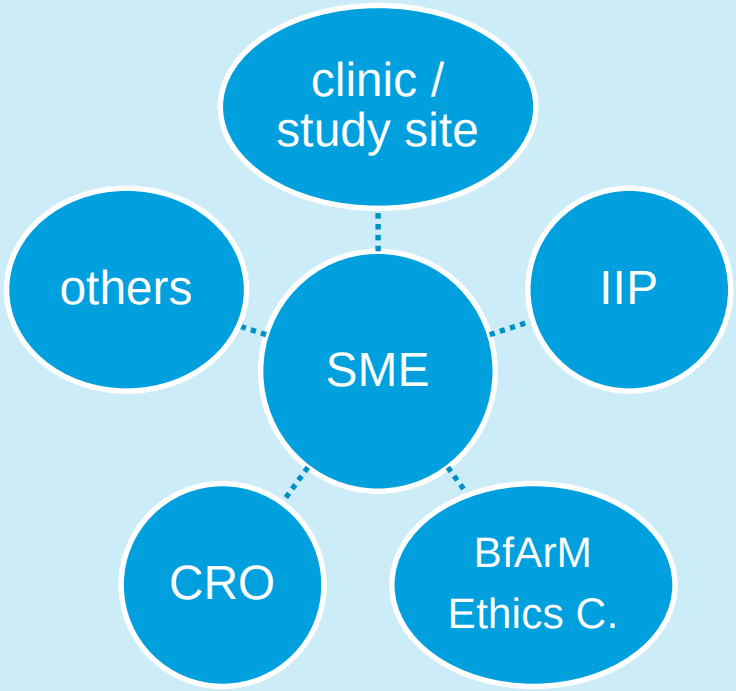
Two-stage funding procedure

Submit project outlines here:
https://www.projekt-portal-vditz.de/

Call for applications: Clinical evidence for medical devices



Funding rate

- Training aid: 50 % + boni
- Innovation aid: 50 %

Financing volume/(period)

- demand-oriented

Endpoints

- Modul 1: Application for clinical trial BfArM
- Modul 2: End of clinical trial

IIP: Industry in Clinic Plattform

Funded projects: Examples

Belegen der klinischen Evidenz der antibakteriellen Wirksamkeit silberbeschichteter Implantate zur Infektionsprophylaxe (KV-Aglm)

Point of Care Testsystem zum Nachweis von HPV (IVDR_CYCLER)

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Ansprechpartner

Projektträger Gesundheitswirtschaft
VDI Technologiezentrum GmbH
Bertolt-Brecht-Platz 3
10117 Berlin

Telefon: 030/275 95 06 – 41
Email: pt_gesundheitswirtschaft@vdi.de

Skizzeneinreichung
https://www.projekt-portal-vditz.de/

„Klinische Effizienz belegen“
Dr. Diana Khabipova, Dr. Monika Weinhold

Thanks for your attention!