

INCENTIVES IN GERMANY

- Evidence Studies & Investment-

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Market entry strategy for Germany

Funding to support a market entry of a medical technology innovation in Germany.

Simplified basic scenario for an enterprise (SME) intending to validate and commercialize a medical technology innovation in Germany and internationally.

Status quo of the project:		
 Medical technology innovation has been brought forth 	Enterprise commercialization strategy:	
	- Germany is a target market	Enterprise financial need:
	 Clinical evidence study is necessary 	 Financial support for running a clinical evidence study
		 Financial support for facility establishment in Germany

General introduction

Germany offers funding instruments for multiple business activities.

Incentives in Ge	ermany			
Investment	Working Capital	R&D	Personnel	Specific Purposes
Financing supp	ort by any of the follo	wing funding instrum	ients	
Grants	Loans	Guarantees	Equity Capital	Mezzanine Capital
The combination of funding instruments is basically possible.				

Grants for clinical validation of medical technology solutions (1)

Funding is offered to transfer medical technology innovation into medical care.

Funding program "Transfering medical solutions into patient care" (Program term: 31.12.2026)

- Objective: Fast innovation implementation of medical technical industrial projects
- Support: Clinical validation projects of
 - Innovative medical products/ risk classes: IIa, IIb, III
 - In-vitro diagnostics/ risk classes: B, C, D
- Funding: Non repayable grants, up to 50% of the eligible costs for clinical evidence studies (effectiveness/performance)
- Focus: SMEs (EU-definition)
- Funding period: Appropriate project term adjusted

Module 1:

Qualification phase/ Evidence study concept

Module 2: Implementation phase/ Study implementation

Grants for clinical validation of medical technology solutions (2)

"Clinical Evidence" program is structured in modules to meet innovators' needs.

Module 1: Qualification phase/ Evidence study concept

Eligible costs:

- Costs for establishing of relevant clinical validation expertise
- Costs of qualification, personnel, advisory costs etc.
- Evaluation costs of existing clinical data, costs for feasability studies etc.

Module 2:

Implementation phase/Study implementation

Eligible costs:

- Costs for clinical trials (mono-/multicenter studies)
- Process management and quality control, documentation/reports, data management, auditing

Note: Commercialization plan of the results in Germany and European economic area (EEA) is required.

Grants for clinical validation of medical technology solutions (3)

"Clinical Evidence" program has a high quota of funding approval of 76%*.

Two-step approval process for any module

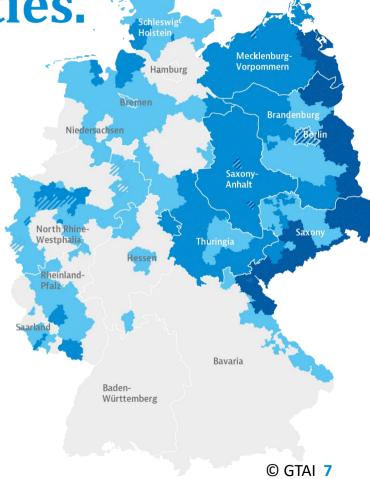
- 1. Step: Project outline (VDI Technology Center)
 - Content of a project outline is predefined
 - Project submission at any time
- 2. Step: Funding application after funding recommandation
 - Content of the formal application is specified

Program promoter

VDI Technology Center GmbH, Berlin www.vditz.de/en/ pt_gesundheitswirtschaft@vdi.de

Investment grants/ Joint task: Improving the Regional Economic Structure Investment support of up to 45% for new manufacturing or service facilities.

Reg	ion/ Enterprise size	Small	Medium	Large
	Border areas	max. 45%	max. 35%	max. 25%
	C region (unemployment + population)*	max. 40%	max. 30%	max. 20%
	C region (population)*	max. 35%	max. 25%	max. 15%
	C region	max. 30%	max. 20%	max. 10%
	D region	max. 20%	max. 10%	max. 200k EUR



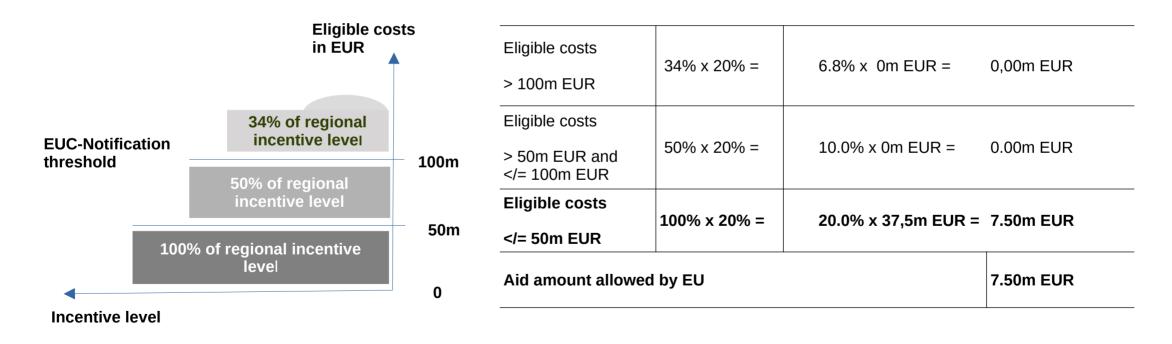
*Note: * In predefined areas in C regions an increased incentive level is confirmed by the EUC.*

Investment grants/ Joint task: Improving the Regional Economic Structure Grants as a funding instrument lowering investment costs.

Objective	 Job creation by setting up new manufacturing or service facilities
Offered in/as	 Specific regions throughout Germany Non-repayable grants, covering up to 45% of the eligible costs
Eligible costs	 Purchase or production costs of new buildings, machinery, equipment, purchase costs of new intangible assets or wage costs for 2y Capped to 750k EUR/ created long-term job
Requirements	 Creation of long-term "quality" jobs Subsidized equipment and workplaces remain on-site up to 5y (SMEs, 3y) 25% of eligible costs must be fianced from non-subsidized sources Bank confirmation that the project financing is secured

Investment grants/ Joint task: Improving the Regional Economic Structure Grant calculation is based on EU regulations.

Eligible investment costs: 37,5m EUR (750k EUR x 50 jobs), incentive level 20%



Public promotional loans **Public loans offer attractive terms and conditions.**

Regional level: Business development banks National level: KfW Group

European level: European investment Bank

- Different loan amounts depending on loan program and loan institutions
- Financing of investment costs, working capital, R&D, specific puposes

Public guarantees

Public guarantees are full-fledge collateral.

Objective	Easing of loans in case of insufficient collateral
Aid amount	Cover up to 80% of the respective loan amount
Availability	 Offered through different programs and institutions Dependent on the loan amount and the investment location
Requirements	 Reasonable project from a macroeconomic point of view Sound business concept

Comprehensive example

Combination of public financing instruments.

New medical technical manufacturing facility:

15m EUR investment (including 1.5m EUR costs for land), 20 new jobs, C-region (20%), equity (20% = 3m EUR)

Equity: 3m EUR

- Financing gap: 12m EUR

Investment grants: 2.7m EUR

(Investment grant program/ Joint task)

- Financing gap: 9.3m EUR

Public loan: 9.3m EUR

(Public guarantee additionally)

- Financing gap: 0 EUR

Grants for R&D

Grants for R&D are available at regional, national and European level.

Regional level: Programs of the federal states National level: Future Strategy Research & Innovation

European level: Horizon Europe

- Aid intensity depends on:
 - Company size
 - Research category: Fundamental research/ Industrial research/ Experimental development
 - Degree of cooperation with partners (SMEs, research instituts, universities)

R&D results have to be commercialized in the region of the program's source.

• Federal state/ Germany/ Europe

Germany Trade & Invest Contact

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