



DFG

Funding opportunities for translational research projects by the German Research Foundation

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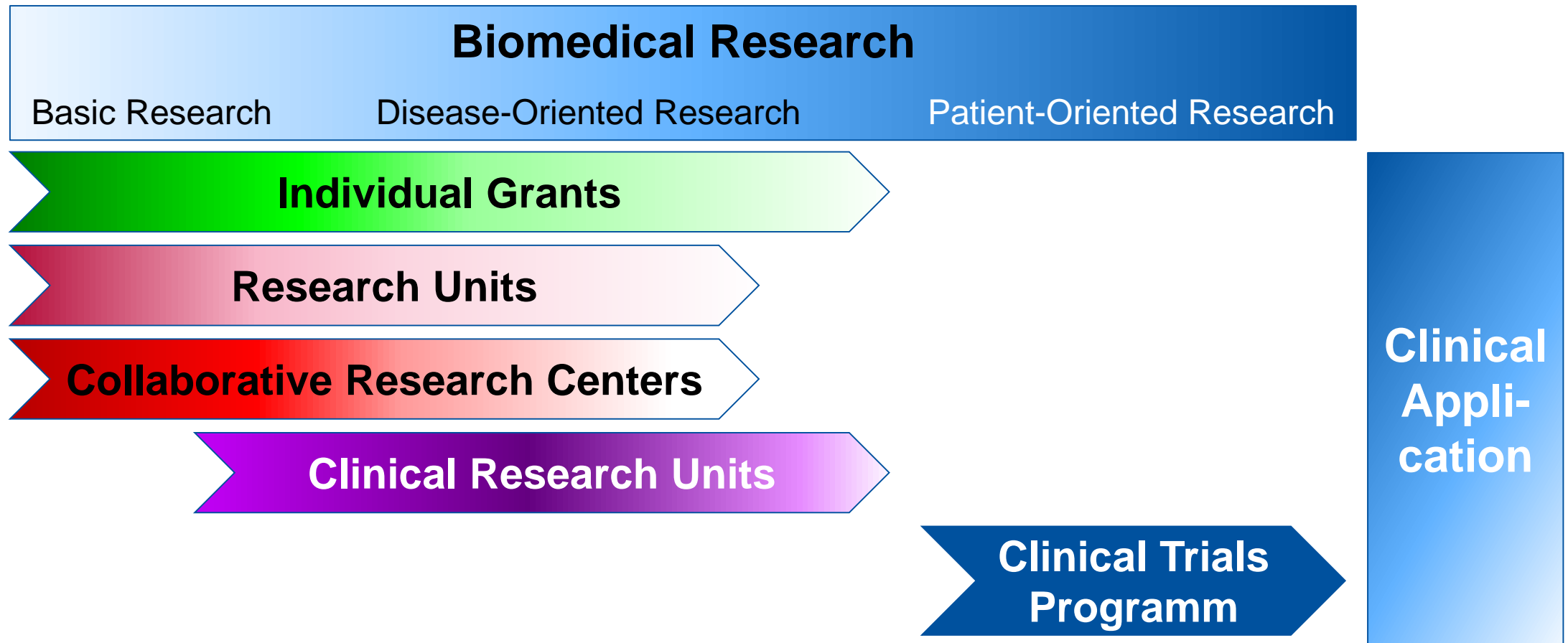


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Deutsche
Forschungsgemeinschaft

German Research Foundation

DFG-Funding of Biomedical Research



DFG-Funding for Clinical Trials

The DFG Clinical Trials Program

Goal: Funding of clinical trials that aim to provide evidence of the efficacy of a therapeutic, diagnostic or prognostic procedure.

Funding schemes:

- **Pilot Studies**
- **Confirmatory Interventional Trials**
- **Observational Trials**

No calls! – Submission at any time!

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Pilot Studies

Goal:

- Create the basis for a later clinical trial

Requirements:

- Must be designed prospectively and it must be clearly stated which questions are to be investigated in preparation for a later study
- Justification of study based on preliminary data
- Design needs to be rigorously oriented on questions to be evaluated
- Biostatistical planning

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Pilot Studies

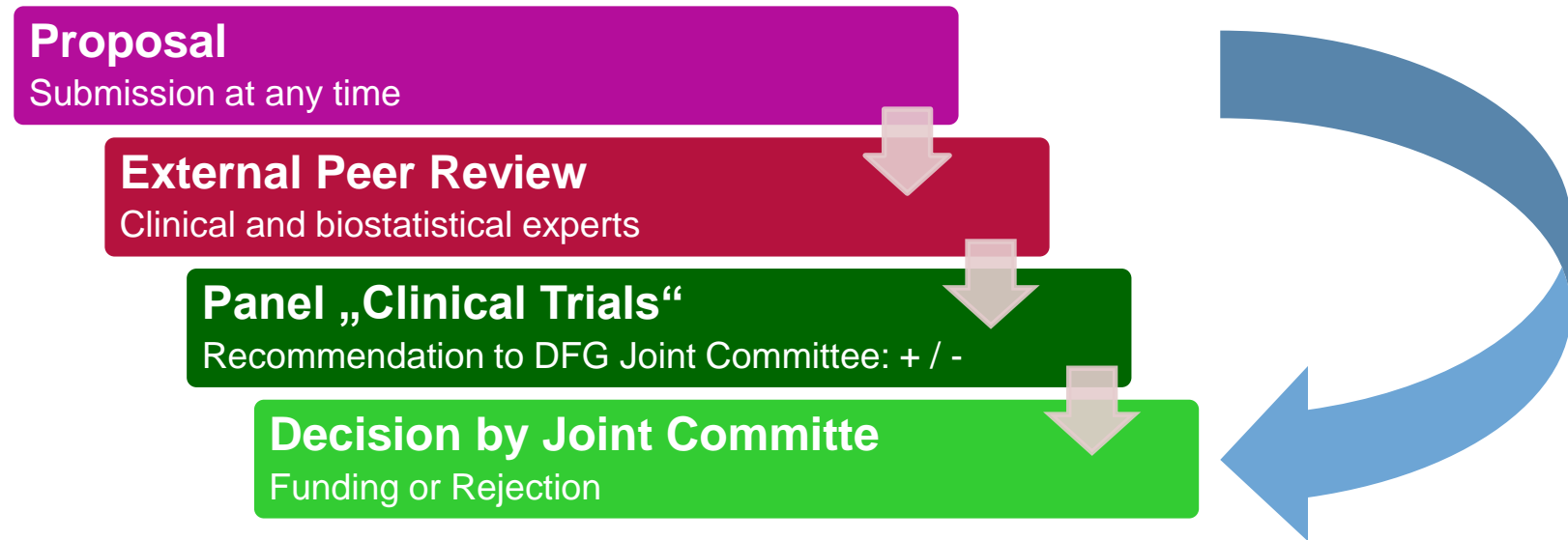
Possible objectives of a Pilot Study may include:

- Evaluating the feasibility of a subsequent larger clinical trial, e.g.
 - regarding the randomization procedure
 - recruitment strategy
 - acceptance of the intervention
- *In preparation:* Obtaining initial safety data and/or dose-finding data
- Acquisition of first signals on the efficacy of the intervention

Funding up to 3 year, usually up to € 350.000

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Pilot Studies – The Decision Process



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Confirmatory Interventional Trials

Goal / Scope:

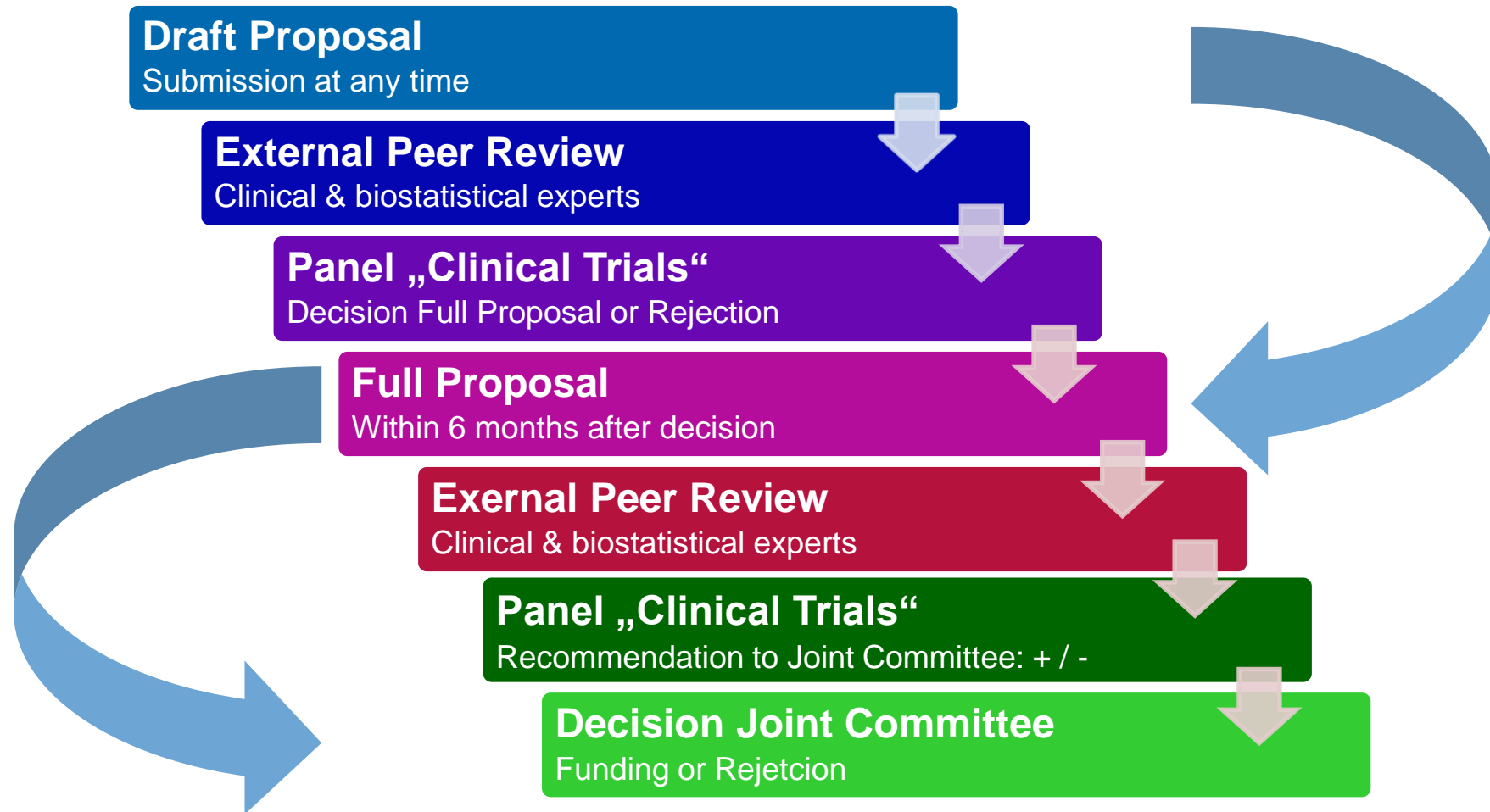
- To demonstrate a significant and clinically relevant effect of a procedure with a high statistical power
- Pharmaceutical / surgical / prognosis / diagnostical studies
- Studies must be prospective in design and aim to confirm pre-specified hypotheses
- Multiple recruitment centers should be involved

Requirements:

- Convincing preliminary work that justifies the study design:
 - acceptance of the intervention
 - estimation of the effect size and number of cases ⇒ Biostatistics!
 - practicability of the recruitment procedure

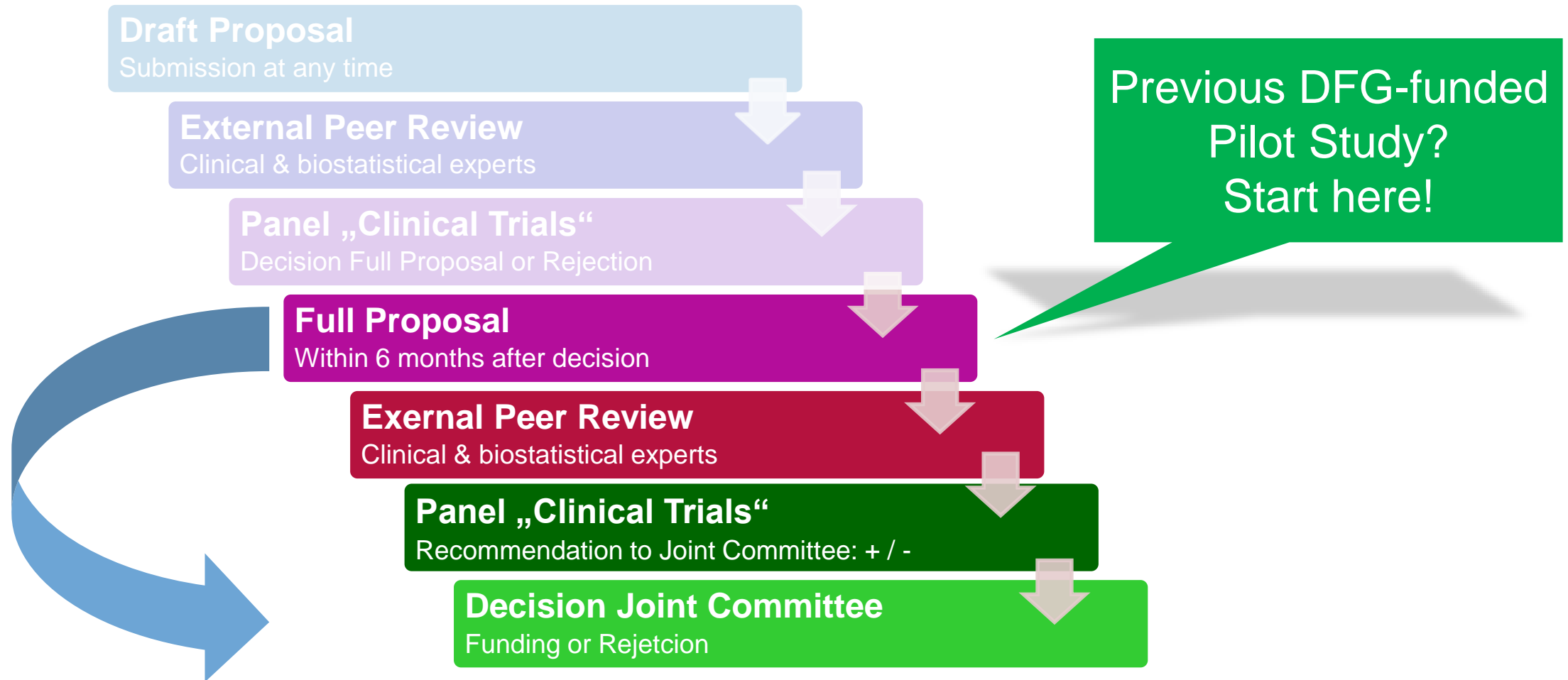
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Interventional Trials – The Decision Process



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Interventional Trials – The Decision Process



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What can be funded?

- ✓ Staff
- ✓ Case payments for recruiting centers
- ✓ Study Medication
- ✓ Consumables / Equipment
- ✓ Insurance fees, fees for Ethic Committees and regulatory authorities
- ✓ Monitoring, traveling costs
- ✓ Publication costs
- ✓ Public outreach

Funding usually in 3 year portions

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How to come to a decision?

**Funding decision is based on
scientific quality and clinical impact**

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How to come to a decision?

Topic / Hypothesis

- ✓ Clinically relevant / international competitive

Qualification of PIs

- ✓ Expertise with Clinical Trials, relevant publications

Evidence / Preliminary Data

- ✓ State of research / pilot study

Planning

- ✓ Intervention und control state-of-the-art and feasible
- ✓ Realistic planning of recruitment / included centers / competing trials?
- ✓ Design of the trial (endpoints, control, randomization, blinding)

Biostatistics

- ✓ Rigorous planning and analysis strategy

Requested funding

- ✓ Realistic and justified



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Some Things to Consider

Planning:

- Get involved with your local experts
 - Clinical experts
 - Patients
 - Biostatistics
 - Clinical Trial Centers

Know the regulatory framework you are dealing with!

Be aware of the recruitment funnel! Plan conservatively!

Plan finances realistically – no need to apply for less than is needed!

Final Slide

A blue banner at the top of the slide features the letters 'DFG' in a large, white, 3D-style font. Below the banner is a horizontal bar composed of several rectangular segments in various shades of blue.

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Thank you very much for your attention!