

# Money for nothing? – Is the Innovation fund the catapult to a new generation of integrated care concepts and a competitive market in health care in Germany?

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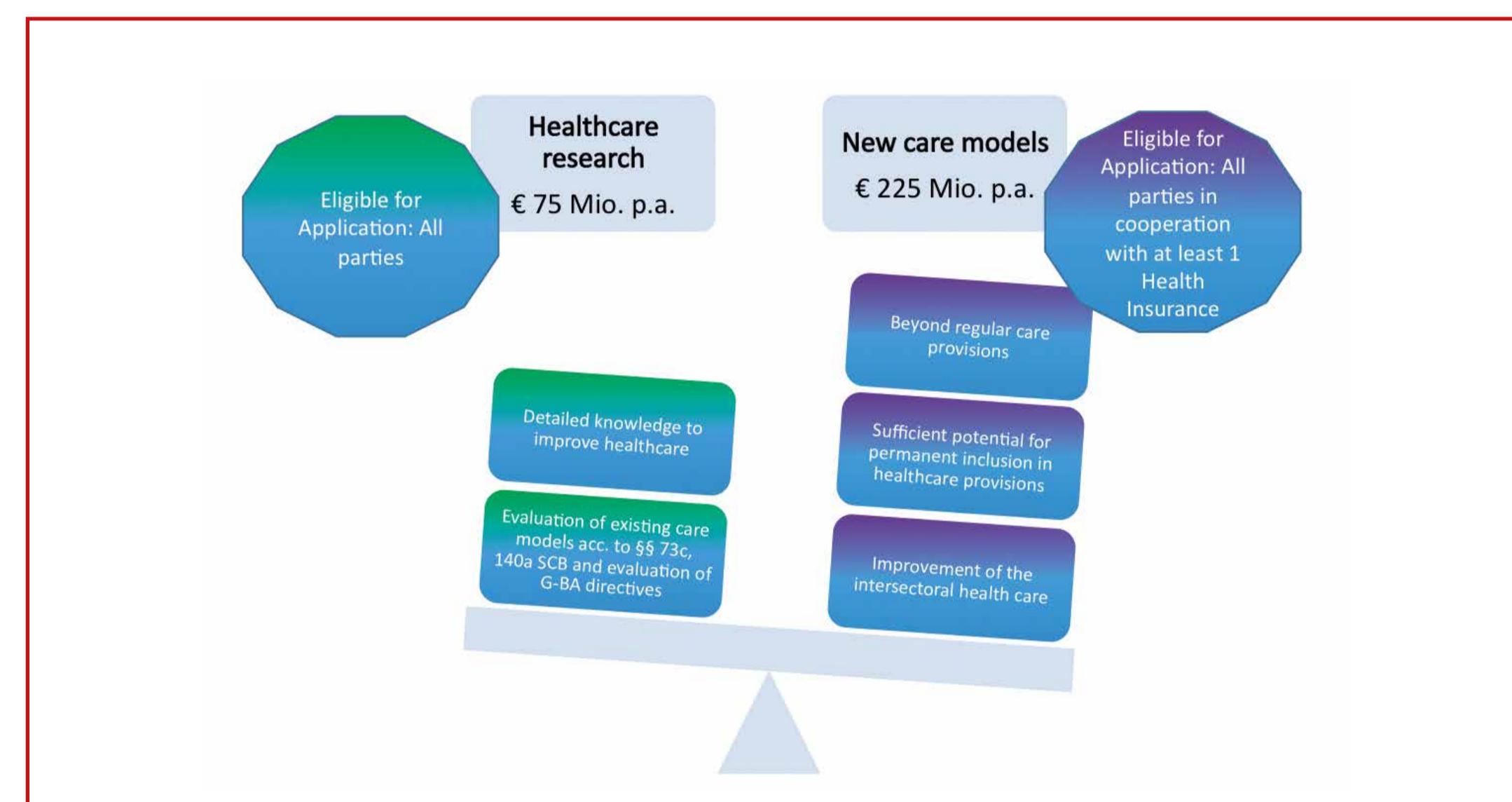
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## INTRODUCTION:

- In 2004 the German health legislation invented a couple of new and innovative care models in order, to increase a more competitive care market and to improve the quality and efficiency of care provisions.
- More than ten years after this invention the market share of these new models are still only about 1% of the total health care market expenditures.
- To put the stalled project back on track last year the legislation abolished major bureaucratic hurdles, improved contracting conditions and invented a funding for innovative care concepts and care research on existing care models – the Innovations fund at the G-BA (joint federal committee, Gemeinsamer Bundesausschuss).
- The Innovations fund has the potential and is expected to:
  - promote the scientific area of care research onto international standards
  - have a positive impact on care structures of the German healthcare system
  - enhance the cooperation of different players in the healthcare system
  - contribute to the creation of a culture of innovation in Germany
  - contribute to the application of high-quality study designs
  - establish a culture of evaluation in Germany
- Germany's Joint Federal Committee (G-BA) has established the Innovation Fund within which it grants 300 Million Euro per year for innovative care concepts (225 Million Euro) and care research (75 Million Euro) – see Figure 1.
- The timeframe for the funding scheme is 2017 – 2019.
- There is a formal tender application process for which eligible applicants can apply. Even that it was not intended initially the application process became highly competitive finally.

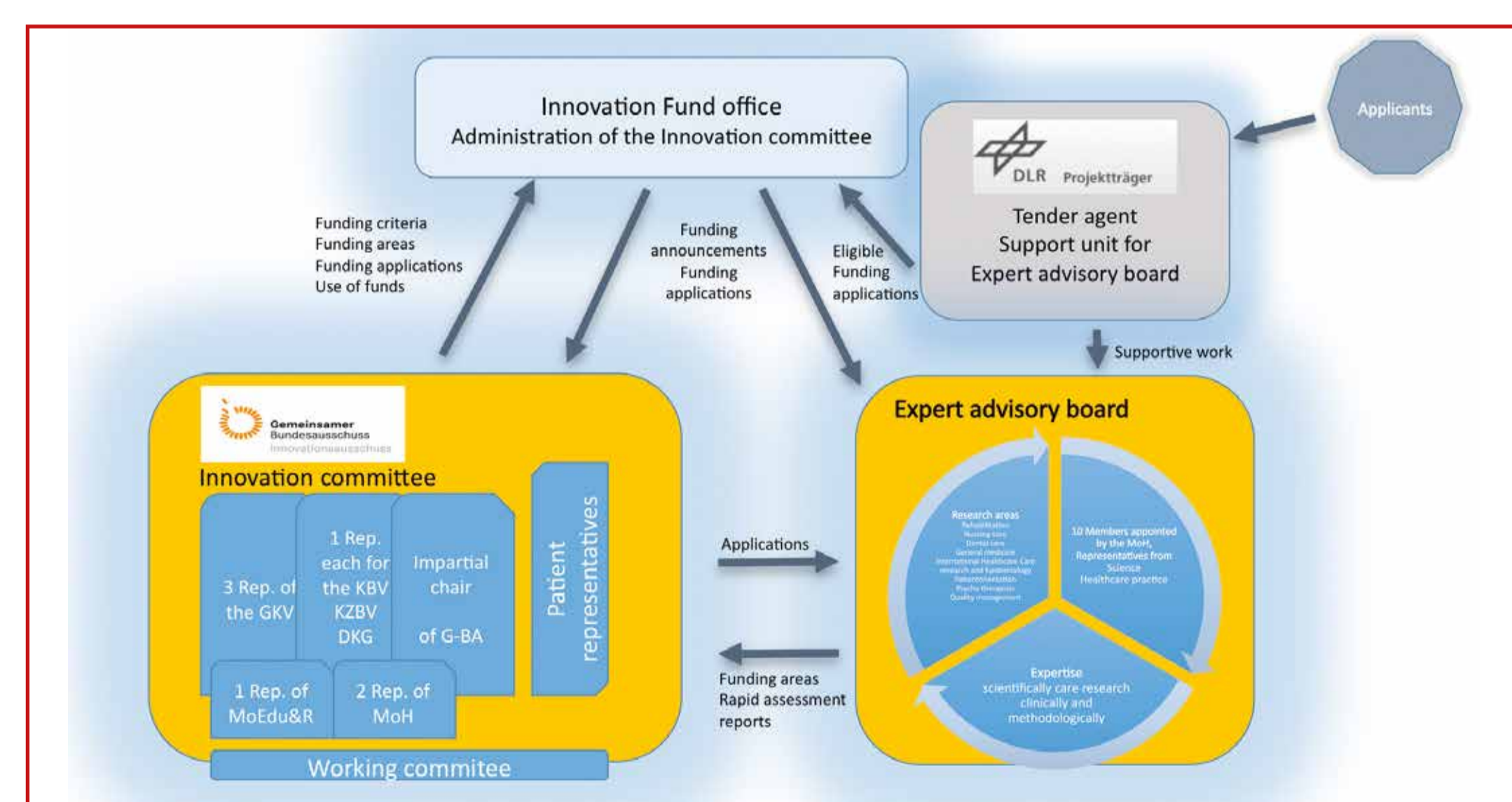
**Figure 1: Innovations fund – budgets for new care models and for healthcare research. Tasks and responsibilities**



## ORGANIZATIONAL STRUCTURE OF THE INNOVATION FUND

- The Innovation committee is the steering body at the Innovation Fund (for Details see Figure 2) – it stipulates the funding announcement, the funding priorities, defines the criteria for funding and conducts calls for expression of interest on the basis of the funding announcement. Finally, it decides on submitted applications; decisions are taken with a majority of 7 votes (of 11 voting rights).
- The Innovation committee directs the funding office, which administers all operations and processes the work in liaison with the DLR Projektträger, the tender agent for the submissions. To the latter all applicants submit their applications and can clarify potential questions during their application process.
- As special function has the Expert advisory board – it conducts rapid-assessments and recommends funding areas to be advertised for application. More details see below.
- Patient organizations have active counselling rights and the right to make a request.
- The rules of procedures of the Innovation Fund regulate the counselling structures, operational procedures as well as principles of the funding procedure for the Innovation committee, the funding office, the DLR Projektträger, the Expert advisory board and other stakeholders and bodies involved.

**Figure 2: The structure on the German Innovation fund**



## EXPERT ADVISORY BOARD

- Advices the Innovation committee.
- Provides recommendations on the content of the funding announcements.
- Conducts rapid-assessments of received applications for funding.
- Make recommendations on funding decisions.
- Before any appraisal of funding announcements or funding applications the expert board must proof whether there're facts for a conflict of interest.
- The involvement of the expert advisory boards within the Innovation fund is regulated in the rules of procedures.

## RAPID-ASSESSMENT REPORT

- The members of the expert advisory board make pre-votes on funding applications upon request by the chairman.
- On this basis a joint appraisal of the funding applications by the expert advisory boards is made.
  - The board appraises whether the requested project meets the legal funding criteria according to § 92a para. 1 s. 2 to 4 SCB V as well as whether the criteria and requirements according to the funding announcement are met and potentially to what extent.
  - The results are summarized in a rapid-assessment report.
  - The given timeframe for the rapid-assessment report and the recommendation is 6 weeks and is binding according to the rules of procedure.
- The recommendations of the expert advisory board must be considered in the decision by the Innovation committee. Any deviations of the expert advisory board recommendations, the Innovation committee has to justify in written.
- Elements of the rapid-assessment proof that:
  - the funding proposals raising a question reasonably precise and according to the funding criteria,
  - the evaluation concept complies with scientific standards and that it can be expected that it leads to scientifically valid results,
  - the funding application is of sufficient relevance for patient care,
  - the implementation of the project is presented transparently and comprehensibly, and
  - the applicant and the cooperation partners demonstrate adequate qualification and previous experience.

## METHODS:

- A descriptive analysis of the first three waves (one for healthcare research, two for new care models) of applications to the Innovation fund regarding timing, requirements (funding criteria), quantity of applications, funding volume and period has been done.
- The analysis was based on a systematically reviewing process of published press releases, presentation of official representatives and professional and lay press publications.
- Results, as known at the time point of the poster development, and an appreciation of the process so far, including potential implications for the future have been addressed in the conclusions.

## RESULTS:

- For the results we have summarized the funding criteria first, followed by the analysis and results of the first three waves including the timing.

## TOPIC SPECIFIC FUNDING CRITERIA FOR HEALTHCARE RESEARCH

### Improvement of healthcare

- Concrete improvement of the quality of care and/or care efficiency, remedy of care shortcomings within the provisions of the statutory health insurance, particular proximity to the patient care practice.

### Qualification and previous experience of the applicant

- Relevant experience and previous projects in care research or the particular research question to be processed (needs to be verified by publications).
- Involvement of partners from sciences and care practice in the writing of the project outline.

### Methodological and scientific quality of the project planning

- Competencies and capacities.
- Consideration of national and international available state of research.
- Multicentre Studies: functioning organisation structures (Project management and measures for quality assurance).

### Utilization potential

- Transfer of the results/strategies for a sustainable implementation.
- Utilization for the analysis and/or the improvement of health care of insured, the further development of clinical practise and/or for structural and organizational improvements.
- All needs to be addressed in the concept of the requested project and described on the structural and processual level.

### Feasibility of the project in the given timeframe

- Realistic work, time and milestone plan for the project timeframe.
- Plausibility of the reachability of case numbers.
- Description of structures and processes of the project.
- Appropriateness of the resource and financial planning.
- Appropriateness and necessity of requested funds for the project provision.

### Additional funding criteria: relevance

- „The requested funding project must address a relevant question for the care provisions within the statutory health insurance. The relevance needs to be plausible demonstrated.“

## TOPIC SPECIFIC FUNDING CRITERIA FOR NEW CARE MODELS

### Improvement of healthcare

- Improvement of the quality of care and/or remedy of care shortcomings.
- Improvement of the care efficiency.
- Optimization of the cooperation within and between different care areas care organizations and professions.
- Interdisciplinary care models.
- Transferability of knowledge on:
  - different regions
  - indications
  - care scenarios

### Proportionality of implementation costs and benefits

- Expenditures for the realization of the project, including the evaluation, need to be in a reasonable relation to the envisaged gain of utility.

### Evaluability

- Methodological and technical capacities and independence of the parties involved.
- Sustainable and outcome oriented evaluation concept.
- The results of the project and its effects for the provision of care with regard to the proof of potential for a permanent adoption in regular care needs to be evaluated on a reliable and accurate data basis.

### Implementation potential

- Scope of feasibility, the necessary steps for the implementation and the transferability of the framework conditions chosen within the project.

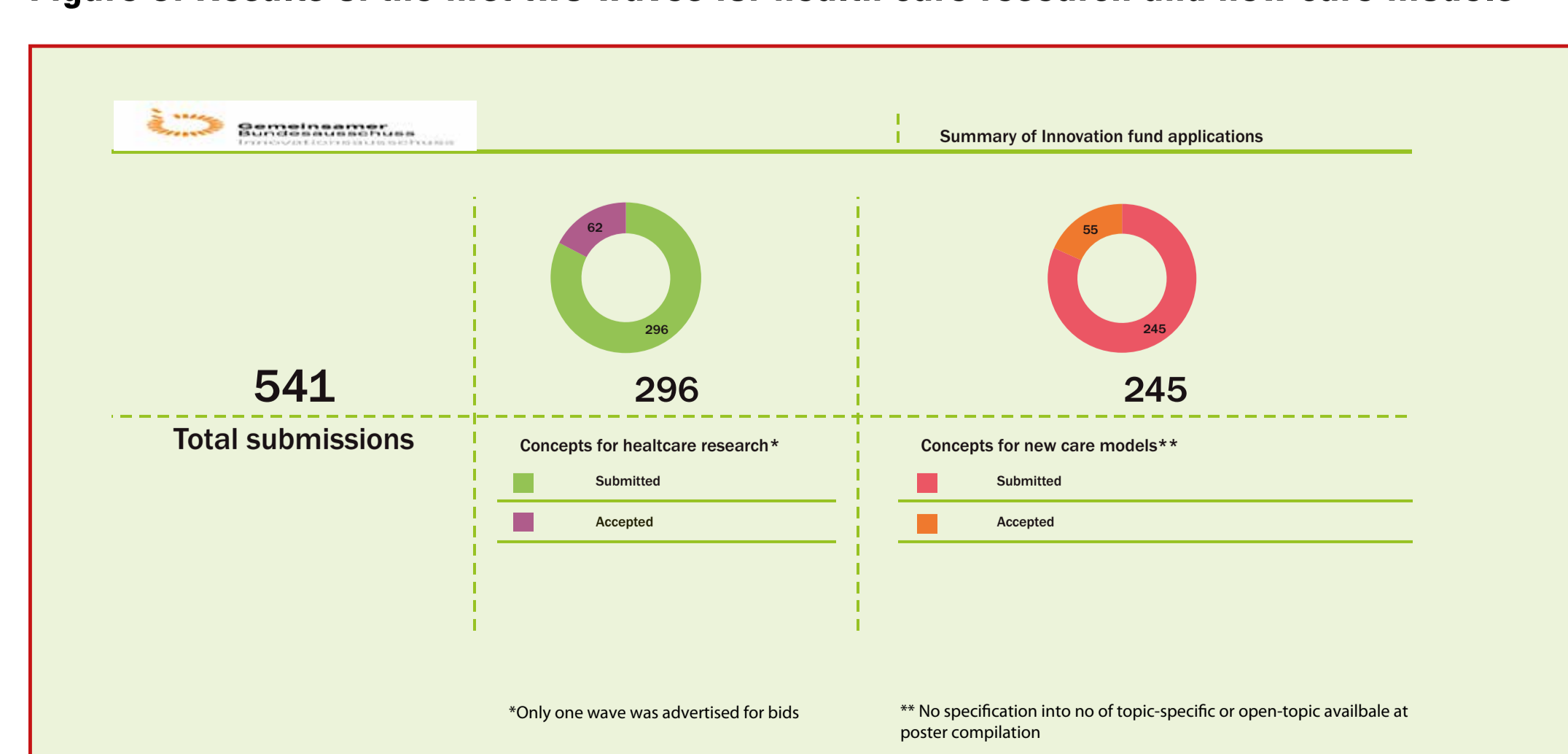
### Feasibility of the model approach

- Realistic work, time and milestone plan for the project timeframe.
- Plausibility of the reachability of case numbers.
- Description of structures and processes of the project.
- Appropriateness of the resource and financial planning.
- Appropriateness and necessity of requested funds for the project provision.

## ANALYSIS AND RESULTS OF THE FIRST THREE WAVES

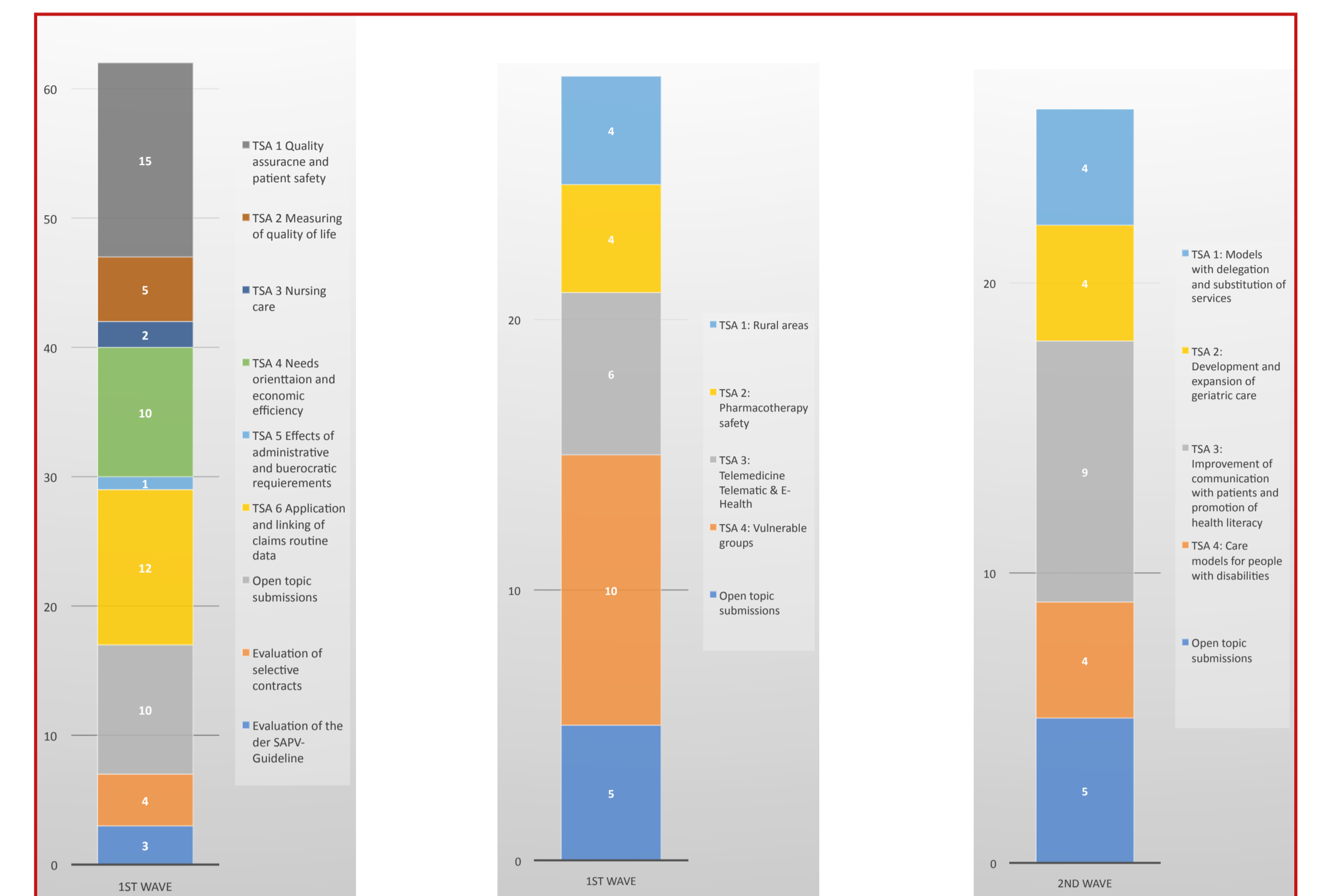
- In total there have been three bidding waves by the Innovation Fund until autumn 2016 which resulted in a total of 541 applications.
- Applications can be made topic-specific, then topics have been defined by the Innovation Fund on proposal of the expert advisory board, according to the overall defined funding area. Applications can also be made topic-open, meaning that the applicant can freely propose a topic in type of a healthcare research or new care model approach.
- For healthcare research in total 296 applications have been submitted (open-topic 93; topic specific 203) and 62 (22%) have been accepted for funding.
- For new care models in total 245 (138 1st wave; 107 2nd wave) applications have been submitted and 55 (22%) have been accepted for funding.

**Figure 3: Results of the first two waves for health care research and new care models**



- For new care models two bidding waves have been called, each providing for open-topic applications and topic-specific applications.
- For health care research only one bidding wave has been announced providing for four different funding areas.

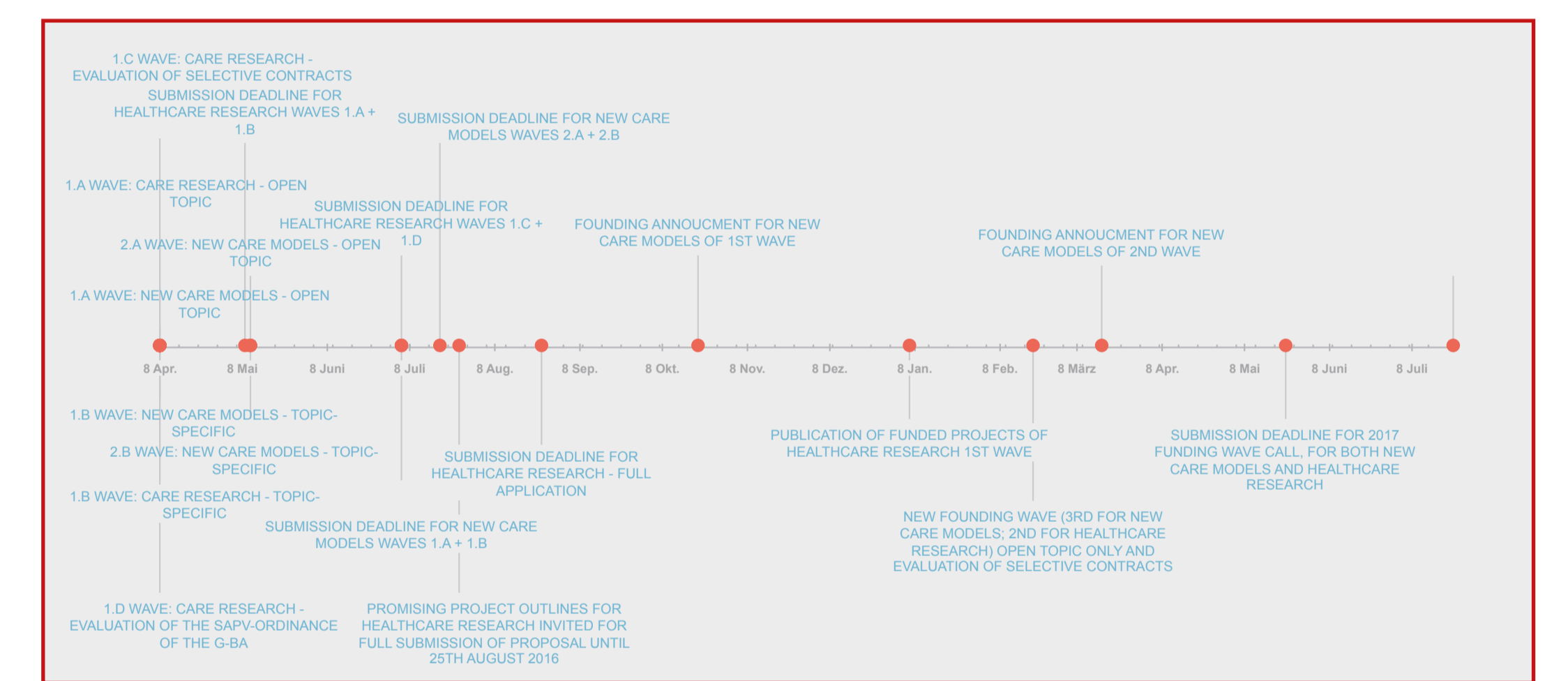
**Figure 4: New care models**



## Timing and Funding allocated

- For the bids different submission deadlines have been given (see details in figure 5)
- Although the expert advisory board has to make their rapid-assessment within 6 weeks after submission due, the Innovation Fund has not defined any specific timelines for their decision.
- It was expected that a decision is made within a reasonable timeframe (e.g. 6 weeks (expert advisory board) + 6 weeks (Innovation committee) in total 3 month) but this is not fully clear yet.

**Figure 5: Timing of the first three waves of the Innovation fund**



- The submitted project proposals show:
  - a high innovation potential
  - a high degree of inventiveness
  - innovative solutions for healthcare provisions
- Since the beginning of the funding opportunities until April 2017 about 700 funding requests have been submitted to the Innovation Fund. This means that since the announcement of the 3rd Wave, on 20.02.2017, 159 new proposals have already been submitted.
- For the Innovation committee's decision, the comfortable difficulty aroused that due to the amount of applications and their high eligibility for funding, the funds for 2016 and 2017 are already oversubscribed.
- In total the requested funding of the first wave only is 1,7 billion €, more than the fivefold of the available funds.
- Even though the funding could not provide funds to all applications, the distribution on all topic specific funding areas could be achieved in a fair balance.
- Since the decisions of the Innovation committee on the funded projects almost 800 grant letters have been sent to the applicants:
  - 422 notice of rejection
  - 259 funding announcements
  - 91 grant letters (healthcare research and 1. Wave New care models)
  - 26 Notice of amendment with condition precedent
  - 26 Notice of amendment with condition precedent

## CONCLUSIONS:

- The Innovation committee has made the first funding decisions for the first two waves for new care models and the first wave for healthcare research.
- The Innovation Fund announced a 3rd wave mid February 2017 although the funds have already oversubscribed. This means that the majority of concepts will not be funded initially, although the quality of applications seem of reasonable good quality and had potential for innovation in the German healthcare provisions. But what will happen now with all the refused project proposals with promising approaches - plenty of innovation back in the drawer? The legislative intention was to stimulate an innovation climate that brings new and better forms of provision, that go beyond the regular care. Especially those should be funded that improve the cross-sectoral care and have the potential the become included permanent into the care provisions. It's more than just a mere blemish that there is no solution in the total concept of the Innovation Fund for all the refused proposals!
- Only the time will tell if the innovation climate has brought a promising flood into the system, independent if subsidised by the Innovation Fund or financed by the project consortium itself.
- Subject to criticism was that a potential "greyhound-race" lead to applicants losing out! Even though the Innovation Fund still maintains the promise that there is a competition among the best proposals but not about who is the fastest, many experts raise doubts. They deem the public policy goal as failed because it does not stimulate any true competition in the health system where all concepts compete while full-filling three important requirements to receive funding:
  - A defined project design before conclusion of contract
  - Obligation to evaluate the programme based on common scientific criteria
  - Obligation to publish the evaluation results.
- Recent criticism as well was raised as potentially the time between funding announcement and the official subsidy note, which then actually releases funding installments, is often quite delayed. Which made it necessary to organize an interim financing for some of the project organisations.
- Still an open question is how the funds may be transferred beyond 2019. It is assumed that after the elections to the German parliament in autumn 2017, that the new government will release an amendment which allows the transformation to later years.

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