



BeNeFIT Trials programme – First Call

Call text

January 2018

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1. BACKGROUND

The Belgian Health Care Knowledge Centre (KCE) and ZonMw, the Netherlands Organisation for Health Research and Care innovation, signed an agreement on 30 November 2017 to invest a maximum of 6 million euros for collaboration in this call.

The effectiveness of existing health care interventions is not yet sufficiently compared in clinical trials (e.g. comparisons between medication and surgery, operating or not operating). Moreover, a lot of research is not practice-oriented, so the results are not immediately usable in daily medical practice. Comparative, practice-oriented studies contribute to better patient care and more efficient use of public resources. Therefore, in the Netherlands the government finances such studies through the ZonMw programmes 'Rational Pharmacotherapy' and 'Health care efficiency research'. In autumn 2015, the Belgian Minister of Public Health, Maggie de Block gave KCE the mandate to select and fund such comparative effectiveness clinical studies programme (KCE Trials).

KCE trials and ZonMw are now joining forces to launch a joint programme under the name 'BeNeFIT'. After all, many questions are relevant to health care stakeholders in both countries and by working together clinical trials can be carried out more quickly and efficiently.

The purpose of BeNeFIT (Belgium-Netherlands Funding of International Trials) is that Belgian and Dutch institutions together carry out non-commercial practice-oriented research which is immediately relevant to patients, caregivers and policymakers in both countries.

This pilot project offers researchers, but also the financing government organisations, a unique opportunity to support and learn from each other.

KCE and ZonMw closely collaborated to set up the BeNeFIT call and jointly developed a common selection process integrating approaches from both organisations, unique for this BeNeFIT call.

2. AIM OF THE CALL

The aim of the call is to provide funding for clinical trials that compare the effectiveness of existing health care interventions that are already in use in a given indication, e.g. comparisons between two medications, medical therapy versus surgery, trials investigating optimal timing of surgery etc. The research should be pragmatic and practice-oriented.

Each BeNeFIT Trial should be of a non-commercial nature. The different treatment options that are compared under a BeNeFIT non-commercial trial should concern treatments that are (or have the potential of being) reimbursed by health care payers in Belgium *and* The Netherlands.

Each BeNeFIT non-commercial trial (hereinafter "trial") should have the potential of generating results with an immediate and important impact on the efficiency of the health care systems in Belgium *and* The Netherlands.

3. CRITERIA

3.1 Who can submit to the BeNeFIT call?

Research teams from Belgium and the Netherlands can apply to this call. The sponsor* (the main applicant, who shall also be the sponsor of the Trial under ICH/GCP) should be located in one of the two countries and should be supported by a national coordinating centre in the other country. Both Belgian and Dutch centres should participate, ideally with a good regional spread. In Belgium, both French-speaking and Flemish centres should participate.

* As defined in [ICH-GCP](#)

Belgium

- If the sponsor is located in Belgium, the sponsor should qualify as non-commercial sponsor under the applicable laws, including the law of May 7, 2004.
- Participating centres should include at least one centre from the Flemish and the French speaking part of the country.[§]

The Netherlands

- If the sponsor is located in the Netherlands, the sponsor should be a research or care institution.
- At least one of the participating institutions in the Netherlands should be a non-academic hospital.[§]
- Studied interventions should be (or have the potential of being) reimbursed under the “Basic Health Care” Act and/or the “Long Term Care” Act packages (“basispakket Zorgverzekeringswet” and “Wet langdurige zorg”) in The Netherlands.
- Studies should fall within the scope of the “Health care efficiency research” (DoelmatigheidsOnderzoek) programme or the “Rational Pharmacotherapy” (Goed Gebruik Geneesmiddelen) programme of ZonMw. For detailed information please consult the [website of ZonMw](#).

[§]If not possible, please justify

In the country where the sponsor is not located, a national coordinating centre should be assigned. The national coordinating centre is responsible for coordinating the trial in close collaboration with the sponsor. Tasks assigned by the sponsor to the national coordinating centre may include managing the submission of the trial to the applicable bodies and translating and adapting documentation for its country.

3.2 Budget and duration of proposed trial

For both the budget and duration of the proposed trial, no maximum amount is defined. The proposed budget of the trial must be reasonable and commensurate with the work involved. A thorough evaluation of the proposed budget is part of the total assessment procedure.

The duration of the study should be realistic and be able to generate results preferably within five (5) years. The total maximum available budget for this call is 6 million euros, with the intention to fund 2-3 trials.

3.3 Scope

The BeNeFIT call focuses on comparative effectiveness trials which show clear value for money and have the potential for return on investment (see Annex 1: Selection and prioritization criteria). Comparative effectiveness trials compare the benefits and harms of different treatment options (including no treatment or placebo) that are already in use in the health care system in the given indication but which have never been adequately compared directly (*i.e.* which of 2 treatments work better in a real-life situation). Accepted trial interventions are not limited to drugs or medical devices but also include a broad range of interventions, such as psychotherapy, diagnostic tests or surgery. Proposals will be selected based on the need for evidence in clinical practice and possible efficiency improvement and potential return on investment for the health care systems. The primary aim of the trial should be of a non-commercial nature.

Out of scope:

- Implementation research, defined as “the scientific study of methods to promote the uptake of research findings in practice”
- Health services research that studies the organisation of care (at macro, meso or micro level). This call offers no scope for research involving organizational innovations, such as task rearrangement, offering the intervention at another location or logistical organization of care.
- Development studies, innovation studies
- Prevention, screening (early detection) or tests to predict risk or response. An exception is healthcare-related prevention, including relapse prevention. This is aimed at preventing an existing condition leading to complications, limitations, a lower quality of life or mortality. The target group therefore consists of patients. That is appropriate within this subsidy round.
- Studies that already have been submitted to authorities, ethical committees and/or have already started recruitment
- Interventions that are not eligible for possible reimbursement in at least one of the two countries

3.4 Evaluation criteria

Proposals will be evaluated for relevance and for scientific quality by the BeNeFIT Scientific Evaluation Committee (SEC) (see 4.1).

The evaluation criteria are listed in Annex I. Applicants should make sure that sufficient information is available in their submission for the SEC members to evaluate the submission according to the listed criteria.

4. SELECTION PROCEDURE

4.1 Management Boards

Two boards, the Call Steering Committee (**CSC**) and the Scientific Evaluation Committee (**SEC**), will manage the evaluation process of the call with support of the Secretariat (set up at ZonMw, the Netherlands). SEC and CSC members will not be part of research teams that apply to this call, conform the [BeNeFIT Conflict Of Interest \(COI\) policy](#). Their responsibilities include the evaluation of research outlines and full proposals and the final selection and award of the trials.

- **The Call Steering Committee (CSC)** is composed of representatives from KCE and ZonMw. The CSC will supervise the organisation and the progress of the call. The CSC will make the final funding decision on the proposals to be funded, based on a ranking list provided by the SEC. All decisions concerning the proposals will be taken by the CSC.
- **The Scientific Evaluation Committee (SEC)** is a panel of internationally recognised scientific experts and representatives of patients and the public, responsible for the evaluation of submitted proposals. SEC members must sign a confidentiality form and report any potential conflicts of interest, conform the BeNeFIT COI policy.

4.2 Overview of the selection procedure

Proposals submitted to the BeNeFIT call will undergo a 3-step selection procedure:

1. The submission of an initial research outline (RO) outlining the key information on the research proposal;
2. Invitation to submit a full research proposal (FRP) for ROs shortlisted by the SEC and CSC;
3. Invitation to submit a revised full research proposal for FRPs selected by the SEC and CSC; revised FRPs should include a more elaborated feasibility assessment, see 4.4.5.

4.3 Eligibility check and evaluation of Research Outlines

All submitted ROs will be checked for their eligibility by the call secretariat. Eligibility criteria are listed in Annex I (9.1.1). Please note that ROs not meeting the eligibility criteria will be declined without further review.

Research outlines passing the eligibility check will be forwarded to the SEC members for evaluation. The SEC will evaluate the ROs for relevance and scientific quality, based on the criteria listed in Annex I (9.1.2) and subsequently rank the proposals according to the received scores.

Further prioritization and selection by the CSC can however change the SEC ranking order, based on the following additional criteria:

- Potential return on investment (ROI);
- The regional spread of the participating centres, aiming for a balanced representation of Belgian and Dutch centres (and for Belgium: a good representation of Dutch and French speaking centres);
- The overall budget of the call and the distribution of the budget among the two participating funders. More information on how the budget will be distributed between the two funders can be found in 5.2;
- The distribution of the Dutch budget among the ZonMw programmes. The contribution of ZonMw must be evenly spent to trials that fall within the scope of the ZonMw “Health care efficiency research” programme and the ZonMw “Rational Pharmacotherapy” programme. (A maximum of 55% of the Dutch budget can go to one of the programmes).

More precisely, the CSC can decide in consensus not to shortlist one of the best ranked ROs (based on SEC scores) but give priority to lower ranked ROs based on the additional criteria, in order to keep an overall portfolio that is balanced in terms of regional and budgetary spread and ZonMw programmes. A maximum of 6 proposals will be selected to proceed to the next round.

All applicants will be informed by the CSC about the result of the evaluation process. Only applicants that were shortlisted will be invited by the CSC to submit an FRP by the set deadline. The letter may contain specific conditions and recommendations to take into account for the FRP.

The invitation to submit an FRP will also indicate the possibility to send a request to the CSC to provide *ad hoc* funding of € 12.500 to support the development of the FRP. This request will be evaluated by the CSC upon its own discretion. The *ad hoc* funding has to be incorporated in your total budget.

To further support the invited applicants in developing their full proposal, a strengthening workshop will be organised on 6 July 2018. We expect the main applicant and a representative of the coordinating centre in the other country to be present.

4.4 Eligibility check and evaluation of Full Research Proposals

4.4.1 Eligibility check

As for the ROs, an eligibility check of the submitted FRPs will be performed by the call secretariat. Eligibility criteria are listed in Annex I (9.1.1). Please note that FRPs not meeting the eligibility criteria will be declined without further review.

4.4.2 External reviewer's evaluation and right to reply (rebuttal)

Each retained FRP will be sent to a minimum of 3 external expert reviewers for a written assessment on the scientific quality and the relevance for clinical practice.

All written reports of the external expert reviewers will be sent to the main applicant. Each applicant will have the opportunity of studying the assessments and commenting on the arguments and evaluations of the external reviewers in a written rebuttal. This stage allows applicants to comment on factual errors or misunderstandings that may have been committed by the external reviewers while assessing their proposal and to reply to reviewers' comments and questions. However, issues which are not related to reviewers' comments or questions cannot be addressed and the work plan cannot be modified at this stage.

4.4.3 Interview and evaluation by SEC

The Secretariat will send the FRPs, review reports and rebuttals to the SEC members for evaluation during the next SEC meeting. In addition, the applicants will be invited by the SEC for an interview, giving them the opportunity to present their proposal and reply to questions from the SEC members. The SEC will subsequently, after consideration of the evaluation criteria (see Annex I - 9.1.2), external reviews, rebuttals and their own discussions, give a score to each FRP for relevance and scientific quality. The scores will be forwarded to the CSC, who takes the final decision on which proposals will be invited to submit a revised FRP. As for the ROs, the CSC will take into account the additional criteria for the final prioritization of the proposals.

Applicants of selected full proposals will be invited to submit a revised FRP that takes into account specific conditions and/or recommendations by the SEC. A revised FRP should include a more detailed feasibility and recruitment plan, see 4.4.5. To compensate the feasibility assessment costs, additional *ad hoc* funding of € 12.500 will be available for selected applicants upon their request. The *ad hoc* funding has to be incorporated in your total budget.

4.4.4 Additional recruitment check

To avoid recruitment problems and a delayed publication of trial results, the CSC requests an additional recruitment check to be included in the revised FRP. In collaboration with the applicant and based on the feasibility provided in the FRP, a third party (CRO) appointed by the CSC will visit participating sites to check accrual commitments and predictions. More detailed information will be provided to applicants that are invited to submit a revised FRP at that time.

4.4.5 Review of revised Full Research Proposals

Review of the Revised Full Research Proposals will consist of an evaluation and scoring for relevance and scientific quality by the SEC. There will be no second review by external expert reviewers and no interview of the applicants at this stage. Scores assigned by the SEC will result in a ranking of the proposals that will be forwarded to the CSC.

4.5 Funding decision

Based on the final scores for relevance and scientific quality, the CSC will take the final funding decisions. The proposals will be selected for funding following the order of the SEC scoring, taking into account the overall budget of the call, the contributions of each country, the regional spread of participating sites (for Belgium including Dutch/French speaking), the contribution for each ZonMw programme (“Health care efficiency research” and “Rational Pharmacotherapy”) and potential return on investment.

The contribution of each country cannot exceed the amount attributed to the call by that country. If during the prioritization process, one of the countries has reached its budget limit, no additional projects can be funded. It is thus possible that a country will not spend its total budget. To maximize the funding opportunities within this call, projects that have a balanced representation in the two participating countries (and for Belgium, in the different regions) will be prioritized. Also, if the contribution of a ZonMw programme reaches its limit, no additional projects that fall within the scope of that programme can be funded (see 4.3).

5. SUBMISSION PROCEDURE

5.1 Online portal

Proposals should only be submitted using the submission portal of ZonMw called [Projectnet](#). **Deadline** for the submission of ROs is **8 May 2018 at 14:00 h**. Submissions on paper will not be accepted.

First time users should first create an account. Practical information can be found in the [manual](#). *Please note that your institution may not be listed in the Projectnet database yet, in which case you have to put in a request to add your institution. Processing your request may take up to 24 hours, so please do not postpone the submission process to the last moment.*

Some data need to be completed directly online. The proposal itself needs to be written using [the Research Outline form](#) for this BeNeFIT call. To complete the form, please read the guidance notes in the form carefully. A detailed budget should be submitted using the dedicated [budget tool](#), for which separate [guidance notes](#) are available. The completed Research Outline form (pdf) and budget tool (Excel) should be uploaded as attachments to your online submission in Projectnet.

For technical questions, you can contact the ZonMw servicedesk via projectnet@zonmw.nl.

For content related questions, please contact BeNeFIT@zonmw.nl or Trials@kce.fgov.be.

For questions related to the budget tool, please contact Trials@kce.fgov.be.

5.2 Budget

The budget of the proposal should be submitted using the [budget tool](#) designed for this call. It is important for the evaluation and selection procedure that budgets are delineated in a standardised format.

The budget tool differentiates between costs that are considered as sponsor costs and site costs. All sponsor costs will be split between KCE and ZonMw, who will each pay for 50% of the sponsor costs. Site costs will be funded by the funder of the country of each site. Site costs can differ by country due to price differences and, more importantly, due to the number of recruited patients per country. Therefore, a balanced number of recruited patients in the two countries is encouraged and proposals with a balanced representation of Belgian and Dutch centres (and for Belgium, a good representation of Dutch and French speaking centres) will be prioritized.

Please note that once the budget is agreed upon, this will be used to develop a payment schedule. In order to stimulate timely patient recruitment and performance of the study as planned, the majority of costs in the payment schedule will be paid on the basis of patient visits completed as planned. Usually, about 20% of the budget will be paid for the first milestone (e.g. signature of research agreement or grant letter), 5% to 10% for the trial report and a final 5% when the scientific publication has been submitted. The rest of the money is split based on accrual milestones. Follow-up of milestones and payments will be organised with the funding entity (ZonMw or KCE) of the country of the sponsor.

6. FINANCIAL AND LEGAL ISSUES

6.1 Funding model

The BeNeFIT partners (KCE and ZonMw) have agreed to launch a joint call using the “virtual common pot” funding mode. This means that national funding will be made available through the national funding organisations according to national regulations. Once an applicant has been awarded funding for a proposal (the “**Sponsor**”), the partner from the country where the Sponsor is located shall act as the main funding entity for the applicable BeNeFIT non-commercial trial (the “**Funding Entity**”).

6.2 Funding contracts

6.2.1 Terms and conditions

All trials granted and performed within this call are subject to the BeNeFIT terms and conditions in accordance with the following:

- If the main applicant is located in Belgium, it shall sign a research agreement with the relevant Funding Entity that incorporates the BeNeFIT terms and conditions. The draft research agreement will be available in the KCE and ZonMw websites by 31 January 2018.
- If the main applicant is located in the Netherlands, the applicable grant conditions published on the call website shall reflect said BeNeFIT terms and conditions, as will be also stated in the award letter. The draft grant conditions will be available on the KCE and ZonMw websites by 31 January 2018.

For the avoidance of any doubt, the BeNeFIT terms and conditions shall be identical for Belgian and Dutch applicants; only the manner in which these BeNeFIT terms and conditions are implemented (through a research agreement for Belgium and through grant conditions for the Netherlands) will differ.

Please note that KCE and ZonMw, the Funding Entities, shall remain entitled at all times to postpone, suspend and/or withdraw any research call (even during the negotiation of the research agreement) upon their own discretion and that the Funding Entities shall under no circumstances be obliged to select any pending Full Research Proposal (FRP), enter into a research agreement or issue an award letter after FRP selection. Applicants can withdraw their submission at any time before signature of the research agreement from the Belgian Funding Entity or receiving the award letter from the Dutch Funding Entity.

6.2.2 Consortium agreement

Each trial will be performed by a consortium, consisting of the main applicant, the national coordinator in the other country and several research partners.

Changes to the budget or the composition of consortia cannot occur, unless there is a good justification. Any minor changes have to be well justified and the Call Steering Committee will decide upon the proper action to be taken. However, in case of major changes, an independent expert can be consulted to help with the final decision of the Call Steering Committee. The sponsor or any of its consortium partners shall inform the respective Funding Entity of any event that might affect the implementation of the trial.

The project consortium partners must sign a consortium agreement (“CA”) for cooperation. The consortium partners are strongly encouraged to sign this CA before the official project start date, and in any case the CA has to be signed no later than six months after the official project start date. Upon request, this CA must be made available for the concerned Funding Entity.

6.3 Ownership of project results

Results and new Intellectual Property Rights (IPR) resulting from projects funded through the BeNeFIT Call will be owned by the Sponsor and/or any of its consortium partners. Since the main purpose of the BeNeFIT Call is to generate results that will serve the general public interests, and specifically the interests of the patients and health care payers, the Sponsor and any of its consortium partners will:

- a. not knowingly or directly exploit the results arising from the study (including any and all trial data and any and all IPR arising therefrom, trial report, etc.) in any way that is or could be detrimental to such interests;
- b. use best efforts to disseminate the trial results by disclosing them to the public by appropriate means, including in scientific publications and
- c. provide a full access right of the trial data to each of KCE and ZonMw, the Funding Entities. This access right will be non-exclusive, worldwide, irrevocable, unlimited, royalty-free and transferable, including the right to sub-license, for any non-commercial research purposes, public health care services purposes, and/or for designing, evaluating, and/or implementing policies or programmes in connection with or related to health care, health economics, pharmacoeconomics and/or social security.

In accordance with the principles set forth above, the commercialization of the results is not and should never be the main aim of the Sponsor.

Co-funding is allowed but the Co-Funder should accept all the principles set forth in the BeNeFIT terms and conditions.

7. LINKS & DOWNLOADS

- [ZonMw Projectnet portal](#)
- [Research Outline form \(Word\)](#)
- [Budget tool \(Excel\)+ guidance \(pdf\)](#)
- [BeNeFIT potential revenues \(excel\)](#)
- [Template letter of commitment sponsor \(word\) + coordinating centre \(word\)](#)
- [BeNeFIT Conflict Of Interest policy \(pdf\)](#)
- [Timelines \(pdf\)](#)
- [ProjectNet short user manual \(pdf\)](#)

The draft Research agreement template (Belgian sponsor) and draft grant conditions (Dutch sponsor) will be available on the KCE and ZonMw website by 31 January 2018.

8. CONTACT AND FURTHER INFORMATION

Further information on the BeNeFIT Project, the Call and the follow-up is available on the KCE (<https://kce.fgov.be>) and ZonMw (<https://www.zonmw.nl/>) website. It is advised to contact the national contact person for any question regarding the Call (please see national contact details below).

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9. Annexes

9.1 ANNEX I: Selection and prioritization criteria

9.1.1 Eligibility criteria

To be deemed valid and to enter the selection process, your application should:

- Be received before the deadline of 14:00 h on 08 May 2018
- Be submitted through the ZonMw [Projectnet portal](#), using the appropriate form and be readable
- Be written in English
- Include a signed letter of commitment by the sponsor* and the national coordinating centre for the other country (see template for letter of commitment)
- Include a clearly defined research question in the PICO format (Patients, Intervention, Comparator, Outcome)

* As defined in [ICH-GCP](#)

9.1.2 Evaluation criteria

Relevance

Need for Evidence	<ul style="list-style-type: none">• The importance or burden of the health or care problem to those who would use the evidence generated by the proposed trial. In particular, whether the trial would likely lead to improved health and care in Belgium and the Netherlands and contribute to change in daily practice.• What the proposed trial would add to the existing body of knowledge based on a well-documented search for completed and ongoing research.
PICO	<ul style="list-style-type: none">• The trial is a non-commercial trial of interventions in use in Belgium and the Netherlands in the given indication, without limitation in terms of therapeutic domain or type of intervention or comparator.• Studied interventions should be reimbursed already or be eligible for possible reimbursement in Belgium and the Netherlands if trial results show effectiveness.• Trials evaluating new interventions in early development would be excluded. Research into the organisation of care and implementation research are not eligible for the 2018 international call. Also, trials evaluating screening, prevention or tests to predict risk or response are excluded.• The trial intervention(s) should reflect current clinical practice as close as possible.• Outcomes are patient centred and include the core outcome set, if available.

<p>Potential return on investment (ROI) for the healthcare systems in Benelux</p>	<p><u>Highest score</u>: substantial cost savings are expected. Either substantial savings per patient for small populations as well as savings for large populations that are substantial because of the size of the population fall within this category. Interventions with an equivalent effectiveness that result in relevant cost savings compared with existing alternatives also fall within this category.</p> <p><u>High score</u>: Increased patient benefit comes at acceptable extra expense for society.</p> <p><u>Low score</u>: It is very questionable whether the increased patient benefit comes at an acceptable extra expense for society.</p> <p>Research outlines that contain insufficient information to judge the potential ROI will receive a low score.</p>
<p>Implementation</p>	<ul style="list-style-type: none"> • There should be a clear implementation plan, describing how the results will be implemented and will have an impact on daily practice, e.g. via international guidelines and/or reimbursement. Ideally the project will relate to a guideline that is supported by professionals in the two countries.
<p>Patient and public involvement</p>	<ul style="list-style-type: none"> • The funding organisations strongly encourage patient involvement in research. Preferably, the research question should be ranked high by patient panels. The involvement of patients and public in the development of the project (selection of patient-relevant study endpoints, feasibility of trial assessments) and their continued involvement through the lifecycle of the research project is required for submissions to the Call. • A lay summary in English, Dutch and French should be included.

Scientific quality

<p>Design</p>	<ul style="list-style-type: none"> • The trial design would answer the research question proposed. • A pragmatic design is to be selected if this would be most informative. • Trial design should allow for sufficiently long follow-up. • A randomised, multicentre design is highly preferred. • The use of centralised randomisation and e-CRFs are recommended. • Only a limited set of variables, needed for the pre-planned analyses, are to be collected. All variables collected need to be well justified.
<p>Sponsor* (Main applicant)</p>	<ul style="list-style-type: none"> • The sponsor's team has the necessary skills, procedures, facilities and experience in conducting non-commercial multicentre trials and has the ability to comply with all sponsor related obligations. • The investigators in all trial sites demonstrate an expertise in the disease and patient population that will be studied.

Patients	<ul style="list-style-type: none"> • At least two sites in Belgium and two sites in The Netherlands should participate in the trial consortium.[§] • The number of patients recruited in each country should be sufficiently high to justify the country specific start-up and coordination costs. • The number of participating sites is sufficiently high and the investigators have access to a sufficient number of eligible patients such that the planned recruitment period is kept as short as possible while fully respecting the scientific rigour of the trial. In addition, measures are in place to maximally reduce the risk of a delay in recruitment including the absence of competing trials that may hamper patient recruitment. The investigators allow the funding organisations to verify these requirements during a trial site visit.
Timelines	<ul style="list-style-type: none"> • The risk of recruitment delay is considered low. • The trial results at the time of publication should still be clinically relevant. • Each trial should be able to generate results preferably within five (5) years.
Value for Money	<ul style="list-style-type: none"> • The proposed costs of the research are reasonable and commensurate with the work involved. • The costs of the trial are reasonable in relation to the likely benefit of the research to decision-makers, patients and the public. In particular, in addition to the health benefits, the results of the research could lead to net savings for the Belgian and Dutch healthcare systems or the promotion of more cost-effective interventions (return on investment). • Each trial should have the potential of generating results with an immediate and important impact on the efficiency of the health care systems in Belgium and the Netherlands, preferably without the need for an additional research.
Terms and conditions	<ul style="list-style-type: none"> • The terms and conditions of the proposed collaboration between sponsor and the funding organisations, as formulated in the “terms and conditions” of the research contract template (including data sharing, possible commercialisation, etc.), should be acceptable for the applicants’ research team and possible other funders. • Data management plan should be made available when the full research proposal is submitted.
Other external funding	Other funding will be allowed only if “terms and conditions” for the BeNeFIT funding are accepted by all parties.

* As defined in [ICH-GCP](#)

§ If not possible, please justify

9.1.3 Prioritization criteria Call Steering Committee

Prioritization and selection by the Call Steering Committee (CSC) can change the SEC ranking of research outlines or full research proposals, based on the following additional criteria:

- Potential return on investment (ROI);
- The regional spread of the participating centres, aiming for a balanced representation of Belgian and Dutch centres (and for Belgium: a good representation of Dutch and French speaking centres);
- The overall budget of the call and the distribution of the budget among the two participating funders. More information on how the budget will be distributed between the two funders can be found in 5.2;
- The distribution of the Dutch budget among the ZonMw programmes. The contribution of ZonMw must be evenly spent to trials that fall within the scope of the ZonMw "Health care efficiency research" programme and the ZonMw "Rational Pharmacotherapy" programme. (a maximum of 55% of the Dutch budget can go to one of the programmes).

More precisely, the CSC can decide in consensus not to shortlist one of the best ranked ROs (based on SEC scores) but give priority to lower ranked ROs based on the additional criteria, in order to keep an overall portfolio that is balanced in terms of regional and budgetary spread and ZonMw programmes.

9.2 ANNEX II: Timelines BeNeFIT call

Deadlines and meetings applicants

16/01/2018		Opening call on website
08/05/2018	14:00	Deadline submission Research Outline
31/05/2018		Decision eligibility
03/07/2018		First decision letter CSC
06/07/2018		Strengthening workshop – selected applicants only
02/10/2018	14:00	Deadline submission Full Research Proposal
31/10/2018 – 28/11/2018		Prepare rebuttal
28/11/2018	14:00	Deadline submission rebuttal
10/01/2019		Meeting SEC to review FRPs + interview with applicants
22/01/2019		Second decision letter CSC
22/01/2019 – 30/04/2019		Start and organize feasibility assessment Prepare revised FRP (and integrate feasibility assessment)
30/04/2019	14:00	Deadline submission revised Full Research Proposal
07/06/2019		Final decision letter CSC