Advisory report

Patient-friendly access to information about medical research

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0. Summary

The voluntary participation of patients as study participants in medical research is necessary for the success of this type of research. That is why it is extremely important that patients are well informed about the range of options, the results and the opportunities for participation in medical research. In the current situation, however, information about this type of research is not easy for everyone to find and is often difficult to understand. Currently, there is also a large discrepancy between the desired number of study participants and the number of study participants actually participating *('included')* in medical research. A working group has been set up within the DCRF (Dutch Clinical Research Foundation) platform that is focusing on improving the recruitment of study participants. They have taken the initiative to analyse how we can make the information about this type of research more accessible to potential study participants in particular and how these wishes can be fulfilled.

The results from this project confirm the current impression of the DCRF working group that patients hardly ever know about which studies are active ('ongoing medical research') and that, as a result, it is unclear to them whether there are any studies to which they might personally be able to contribute. The results also endorse the importance of improving this situation. There is a clear and strong desire among all participants in this research project to improve the accessibility and comprehensibility of information about medical research. What all these participants are waiting for is one central and reliable source of comprehensible information. This source of information must be accessible through various channels and also able to provide tailored information. The new online national register being developed by the CCMO in collaboration with the National Trial Register plays a crucial role in this. However, in developing this register, different issues need to be taken into account if it is to offer real added value for the patients.

Based on the information provided by the participating patients and those with (practical) knowledge, the following recommendations have been formulated and elaborated upon in this advisory report:

Substantive recommendations	**Implementation recommendations**
Offer the information for patients in comprehensible language and ensure that it includes, at the very least, the treatment being investigated and where the research is taking place.	Work closely with patients with practical knowledge and with experienced organisations at each step of the development.
Ensure that the healthcare providers offer the information and that it can also be found online.	Start the implementation of a national (patient-oriented) research information template as quickly as possible.
Offer information to patients at various times: not only during the diagnosis but during a treatment process.	Invoke collaboration and working methods in one uniform format in the Netherlands.
Ensure that the information comes from a central register and can also be used at other locations.	Provide guidance, transparency and collaboration.

1. Introduction

In order to continuously improve the care for patients, medical research is carried out in the Netherlands. By 'medical research' we mean all studies that look for better ways to prevent or treat diseases and disorders. This is done by testing new (combinations of) medicines, therapies or medical devices, with the participation of study participants (patients or healthy people) and under well-controlled conditions.

The voluntary participation of patients* as study participants in medical research is necessary for the success of this type of research. That is why it is extremely important that patients are well informed about the range of options, the results and the opportunities for participation in medical research. At the moment there are several organisations and registers where information about medical research is available. However, this information is not easy to find for everyone; it is fragmented and is sometimes difficult to understand.

There is also a large discrepancy between the desired number of study participants and the number of study participants actually participating *('included')* in medical research: In about half of the studies, the inclusion is insufficient.[1,2,3,5] The potential to improve inclusion is large and is reflected in, among other things, large differences between hospitals in the number of patients included, which cannot be explained solely by differences in the patient population.[4]

As a result, studies cannot be performed optimally. In the worst-case scenario, the study is not completed according to the protocol and there are insufficient valid results. This can have a direct impact on the healthcare offered in the Netherlands. In addition, this means that study participants are unnecessarily exposed to (incomplete) research. We want to improve this situation.

**This report focuses on patients, because the participation of healthy people in medical research is not a problem.*

1. McDonald AM, Knight RC, Campbell MK et al. What influences recruitment to randomized controlled trials? A review of trials funded by two UK funding agencies. Trials 2006;7:9.
2. Van der Wouden JC, Blankenstein AH, Huibers MJH et al. Survey among 78 studies showed that Lasagna's law holds in Dutch primary care research. J Clin Epidemiol 2007;60:819-24.
3. Damen L, Agt F, de Boo T, Huysmans. Terminating clinical trials without sufficient subjects. J Med Ethics. 2012;38(7):413-6
4. Oude Rengerink K, Bossuyt PMM, Mol BWJ, Hooft L. Timely recruitment of the targeted number of participants perceived as more difficult than anticipated by many trialists – an analysis of a cohort of trials in the Netherlands Trial Register. Thesis 'Embedding Trials in Evidence Based Practice', Chapter 3.
5. Oude Rengerink K, Hooft L, van den Boogaard et al. Why do some centres recruit better than others? An analysis of recruitment rates in 17 randomised clinical trials in obstetrics and gynaecology. Thesis 'Embedding Trials in Evidence Based Practice', Chapter 4.

2. Questions and background

Several parties want to change the current situation. A working group has been set up within the DCRF (Dutch Clinical Research Foundation) platform that is focusing on improving the recruitment of study participants. In this working group, it was found that various factors hamper the recruitment of study participants. One of these factors is that patients hardly ever have sufficient knowledge about which studies are actively looking for participants ('ongoing medical research') or which studies have already been completed. As a result, it is unclear to the potential study participants whether studies are being carried out to which they may possibly contribute.

To change this, information about medical research must be actively shared and be retrievable, reliable and understandable for anyone who may be eligible to participate in this type of research. Information is already available via the existing registers, but people do not make their way here and/or the information is incomprehensible.

At the moment, the accessibility and availability of information about medical research is again being investigated in the Netherlands. That is why the DCRF has taken the initiative and asked the working group to analyse how we can make information more accessible, particularly to patients who are potential study participants. This concerns information about research that is or is not subject to the WMO (*Wet medisch-wetenschappelijk onderzoek met mensen* [Medical Research Involving Human Subjects Act]).

Three questions were important in the preparation and execution of this project:

I. Through which channels and information sources do potential study participants want to be (better) informed of the existence of (and possible participation in) active and recently completed medical studies, and what role can a central register/database play in this?

II. Where and using which terms do potential study participants currently search for information about medical studies?

III. What information should potential study participants be able to find in a central register in order to gain a first impression of the range of relevant medical studies in the Netherlands?

In addition, it has been investigated how these wishes can be fulfilled. The CCMO (*Centrale Commissie Mensgebonden Onderzoek* [Central Commission on Research Involving Human Subjects]) has already indicated to the DCRF *Werkgroep Werving Proefpersonen* (DCRF Working Group Recruitment of Study Participants) that, where possible, it wants to use the information collected from this project and to include the recommendations from this report in the development of the new national register.

3. Objective

The aim of this project is to map out medical research (subject to/not subject to the WMO) and to advise on exactly what type of information that potential study participants are looking for and/or want to receive, and how this information should then be should be provided so that it can be found and understood by the target group. A key role is reserved here for the new national register that is being developed by the CCMO in collaboration with National Trial Register.

4. Methods

Three tools were used for the data collection in this project: a digital questionnaire, personal interviews and a group discussion. The project implementers have tried to achieve the most diverse and representative reflection of the target group (potential study participants) possible, but are aware of the blind spots. After all, there is a wide range of disorders and representative organisations that cannot all be approached and, for example, few young people are members of a patient organisation. The summaries of the interviews, the group discussion and the results of the questionnaire can be found in *Appendix 1 - v, vi and vii*. The complete compiled dataset is available via the Chair of the DCRF Working Group Recruitment of Study Participants (please contact the secretariat via info@dcrf-online.nl).

4.1 Questionnaire

The questionnaire (see *Appendix 1 - ii*) was made available digitally between 17 August and 30 September 2017. The *Nierpatiënten Vereniging Nederland* [Netherlands Kidney Patient Association], *Patiëntenfederatie Nederland* [Netherlands Patient Federation], *Longfonds* [Lung Foundation Netherlands] and *De Hart & Vaatgroep* [Cardiovascular Group] approached their own panel members. In addition, the following organisations used various channels to call on their adherents to fill in the questionnaire: *Borstkankervereniging Nederland* [Breast Cancer Association Netherlands] (BVN), Hematon, *Nederlandse Federatie van Kankerpatiëntenorganisaties* [Dutch Federation of Cancer Patient Organisations] (NFK), *Psoriasisvereniging Nederland* [Netherlands Psoriasis Association] (PVN), *Crohn en Colitis Ulcerosa Vereniging Nederland* [Netherlands Crohn and Colitis Ulcerosa Association] (CCUVN), *Vereniging Samenwerkende Ouder- en Patiëntenorganisaties* [Association of Collaborating Parent and Patient Organisations] (VSOP), *Nederlandse Cystic Fibrosis Stichting* [Dutch Cystic Fibrosis Foundation] (NCFS), Facebook groups PSC and AiH.

4.2 Interviews

Nine personal interviews were held (see *Appendix 1 - iii* for the interview script). The interviewees all had practical knowledge and/or were lobbyists with experience in searching and sharing information about medical research. The interviews took place in September and October 2017 and lasted an average of one hour. Seven interviews took place on site, while two were conducted by telephone. For the list of participants, see *Appendix 1 - i*.

The answers of the interviewees are anonymous and are summarised in this report.

4.3 Group discussion

The group discussion took place on 31 October 2017. In addition to the project implementers, four representatives (plus one subsequent contribution from a fifth participant who was unable to attend) took part from organisations who already offer information about medical research to patients. The list of participants consisted of a study manager from Roche (pharmaceutical company), a research nurse and also a board member of the V&VN Research Professionals (the professional association *Verpleegkundigen & Verzorgenden Nederland* [Netherlands Nurses & Carers, Research Professionals Department], a policy advisor for research at the UMC (University Medical Centre) Utrecht, a patient information and communication coordinator from the IKNL (*Integraal Kankercentrum Nederland* [Netherlands Integral Cancer Centre]) and a developer of a Dutch application aimed at providing information about medical research ('TrialApp').

During this 2.5-hour group session, discussions were held on the current availability and accessibility of information for patients about medical research. The core questions were how this could be improved and what possible role the central register could play. In *Appendix 1 - iv* can be found the manual for the group discussion, including the detailed questions that were discussed.

The opinions and comments from this group discussion are anonymous and are summarised in this report.

5. Results

5.1 Questionnaire

Characteristics of respondents

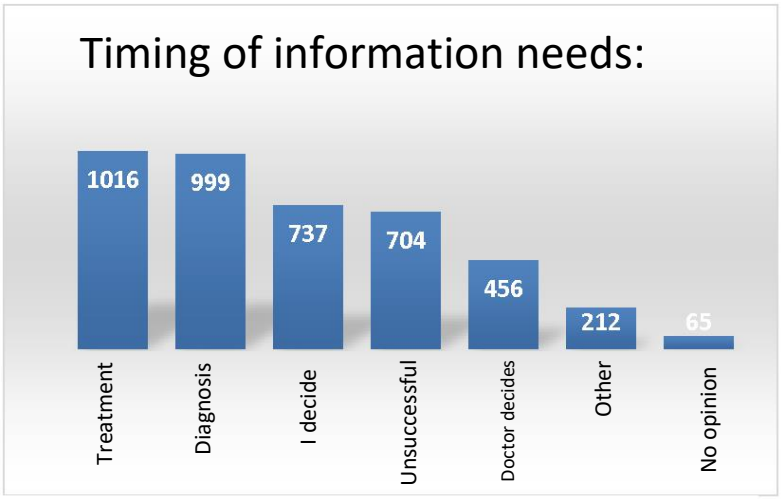
Respondents were approached through a wide network of different patient organisations and 2733 people started completing the questionnaire. In the end, 2041 people completed the entire questionnaire and these results were used in the analysis. Fifty percent of the respondents were male and 50% female. Of all respondents, 51% were between the ages of 36–65 years and 47% were older than 65 years. For the latter group, the results were analysed separately, but there are no strikingly different outcomes compared to the total group of respondents. However, among the 65+ respondents there were relatively many men and the over-65s had no experience with medical research, but said they would like more information about it. There were no respondents under the age of 18. The DCRF recognises the importance of special attention to information aimed at children, but has opted not to examine this separately within this project.

The education level of the respondents was 40% higher vocational education, 28% secondary vocational education, 16% university-educated and 15% who had completed secondary school.

Experience with medical research

Almost half of the respondents (47%) have occasionally participated in medical research and 66% want to know more about it. The respondents are currently looking for information about medical research via an internet search engine. In addition, the websites of (academic) hospitals, patient platforms and organisations and health foundations are regularly mentioned. A few mention newspapers and leaflets in the hospital, PubMed, kanker.nl, clinicaltrials.gov or the CCMO.

Content and the timing of the desired information



The respondents mainly want information about medical research during diagnosis and during a treatment programme (Figure 1). In addition, respondents often indicate that they want information if it becomes clear that the current treatment is not successful. Or they indicate that there is no exact timing: people actively search for information whenever possible.

Figure 1: The desired timing of the information provision.

According to the respondents, the information on medical research must in any case consist of the treatment being examined and the hospitals where the research takes place (Figure 2). In addition, it is also considered important that the possible health and financial benefits and risks are mentioned.

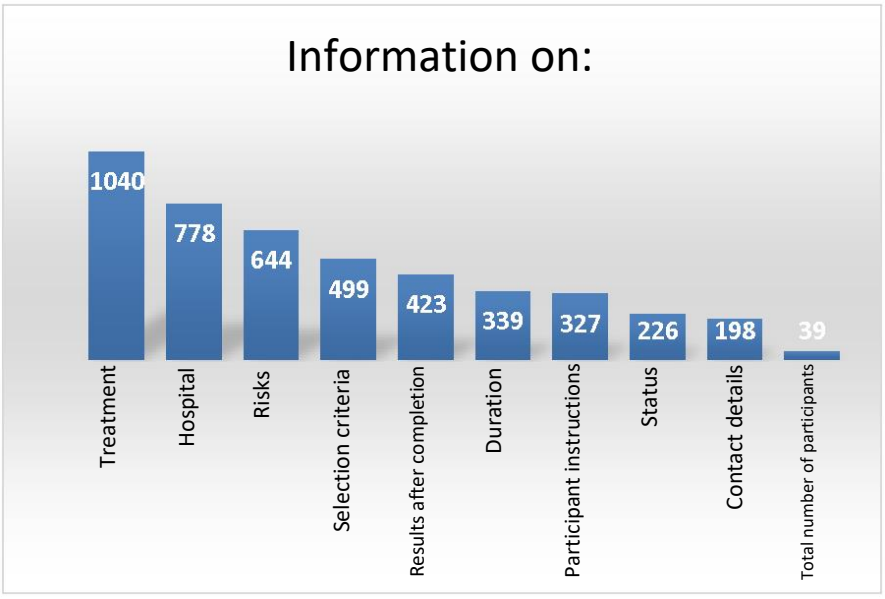


Figure 2: The topics about which people seek information.

Search terms

Respondents were asked which search terms they would use when searching for information about medical research. By far the most common answer is the name of the condition. In addition, 'medication', 'doctor', 'hospital' and 'treatment' are often mentioned. A complete overview of the search terms as entered by the respondents is included in *Appendix 2*.

Finding and receiving information

The vast majority of respondents expect to receive information mainly via their own healthcare provider, such as a treating specialist, general practitioner or nurse (Figure 3). In addition, the health foundations and patient organisations are often appointed as a 'point' where respondents expect to find the information about medical research. An internet search engine, a publicly accessible database and the researcher are also often mentioned.

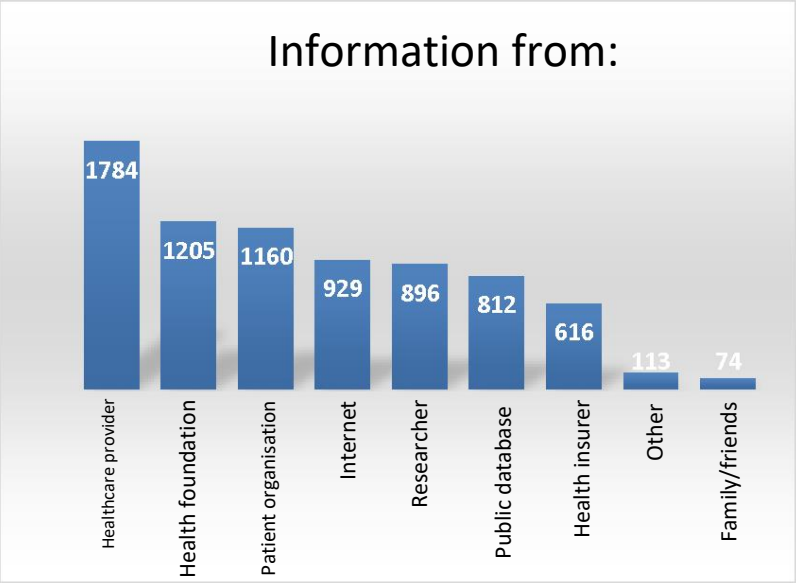


Figure 3: The organisations or persons from whom information is expected to be received.

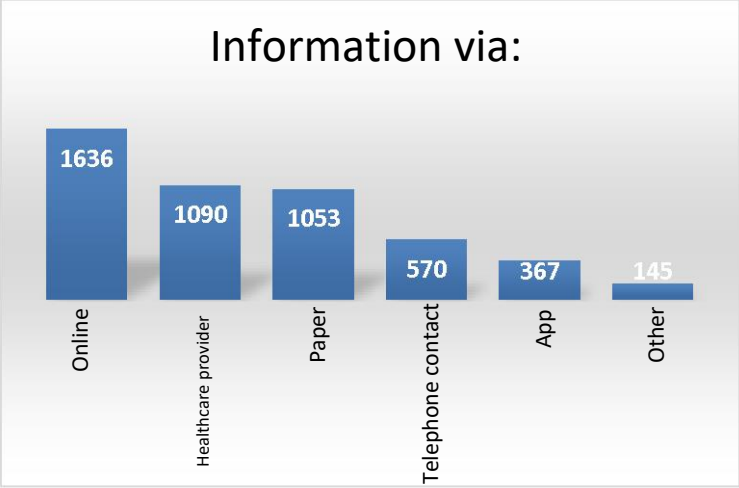


Figure 4: The channels through which the information is preferably received.

By far the majority of respondents prefer to receive information online via a website (Figure 4). In addition, an information brochure on paper and oral contact via a healthcare provider are frequently mentioned. In open comments, 'e-mail' was often also mentioned as a suggestion. Almost half (46%) of the respondents sought information about medical research less than once a month. Another 22% searched more than once a month and 23% do not know how often they searched.

Many suggestions have been made to improve information about medical research. People regularly state that they want to be able to look up information themselves and do not want to be dependent on

the treating physician. There is also a great need for more transparency, feedback of results and information in comprehensible language.

5.2 Interviews

Experience with medical research

The interviewees all have (practical) knowledge and a role as advocate for patients. They play different roles, from directors of a patient organisation to 'patient advocates'. The experience from their personal or professional situation and the associated search for information about disorders varies from around five years to several decades. All are very experienced within their own field.

The reason that people in the past participated or were interested in medical research was generally that they could no longer be treated or were not eligible for standard treatment. They then asked: "What now?"

The search for information about medical research started with questions for the attending healthcare provider (doctor, nurse or pharmacist). A lot of personal research was also done on the internet, where websites of patient organisations, hospitals, umbrella organisations and pharmaceutical companies were consulted to gather information. Subsequently, contact was often sought with a relevant patient organisation. A person became a member of this organisation or asked the organisation or patient panels for advice. If these did not (yet) exist in the Netherlands, individuals made contact with foreign patient organisations (including American organisations) for advice.

View on current availability and accessibility of information about medical research in the Netherlands

The interviewees unanimously agree that the availability and accessibility of information about medical research in the Netherlands must be much better. Terms such as 'poor', 'sub-optimal' and 'is behind the times' are frequently mentioned. Respondents indicated that information about medical research is often fragmented, of varying levels, and not readable by patients and laypeople. The entire process surrounding medical research, including information provision, is slow. There seems to be a jumble of regulations and there is little up-to-date information. However, for many patient groups and seriously ill patients, this is a matter of urgency. The patient also has minimal involvement (and should be more empowered). The patient also often has false hopes and high expectations when medical research is discussed. According to the interviewees, this is the crux of the matter: a balance must be found between offering information about medical research and tempering unrealistic expectations about participation and healing opportunities for the patient.

In addition, it appears that healthcare providers often have too little time and/or knowledge of medical research to provide the patient with information. And information disseminated through the internet or newsletters by patient organisations and advocacy groups has only a limited reach: in many indications only a limited percentage of patients are actually in contact with the

"It is strange that some specialists don't know that their colleague in the same specialty is conducting a study."

patient organisation; the other patients constitute a blind spot when it comes to information provision.

The questions that are important to the adherents of patient organisations are mainly:

- Is there an ongoing medical study for my condition?
- Can I participate?
- Where (in which hospital) and when is a medical study taking place?
- What personal burden is involved (travel, duration, treatment intensity, reimbursement of expenses, etc.)?
- What about safety and side effects?
- What are the latest developments and when will the medicine or treatment studied be available in daily life?

Content and the timing of the desired information

There is a list of topics that each interviewee encounters concerning what information must be provided:

- Which medical studies are being conducted per indication area
- Which centres, doctors and researchers are participating (possibly also abroad/in a border region)
- Inclusion and exclusion criteria
- Personal burden on the patient (travel time and expenses, reimbursements, impact of treatment on quality of life)
- Medical research results from the past or from previous phases
- Details of contact persons for more in-depth information provision

In addition, respondents indicated that it is essential to provide all information in comprehensible language and to have it assessed by a patient panel, for example, for readability.

Respondents unanimously agreed that the time of the first provision of information and the creation of awareness about medical research must be the moment of diagnosis, at the very least. Furthermore, they indicated that it is important to actively offer information about medical research not on just one occasion, but at several times during a patient's treatment process. This keeps the patient informed and prevents a weakening of the awareness of clinical research. Patients experience different emotional phases in the course of a disease. At one moment they are more open to the information than at another. Moreover, people only become interested in medical research once they have become a patient. That connection with the disease creates a boundary. The general practitioner and/or specialist therefore plays an important role in creating and maintaining awareness at the right time for the patient. This varies per patient and per disease, so there is not one specific time that can be designated as a good fit for everyone. One can, for example, look at ways to make the general public aware of the existence of medical research. Related information could, for instance, be shared via commercials on the

"I think it's odd that there is no information at all about research in the doctor's waiting room. After all, this is the obvious point at which to gather information because then people have the time."

government's public information channel Postbus 51, by collaborating with organisations such as the Dutch Pharmacovigilence Centre Lareb, or by placing leaflets in pharmacies in consultation with, e.g., the MEB.

Finding and providing information

Respondents were unanimous regarding how to provide information about medical research: in user-friendly and layman's terms. There is currently too much written 'to' the patient and too little 'together with' the patient. So, ensure patient involvement: let patient panels review communications for readability and, for instance, give the patient the opportunity to review this information online (such as the star system on websites like booking.com). In principle, it does not matter who they receive information from as long as it is given in a complete form and from a reliable source.

The online provision of information could be done via patient organisation websites or platforms such as LinkedIn. In addition, respondents said they paid attention to the provision of information about medical research during conferences or gatherings for patients, for example. Hardcopy information brochures should also be offered in waiting rooms or on the pharmacy wall, for example, so that the 'digitally illiterate' can also be reached.

The interviewees expect the following persons and organisations to play an active role in providing information about medical research:

- **Doctor:** both the general practitioner and the specialist play a crucial role in raising awareness and providing information to the patient. They should be the first to inform the patient about medical research and the potential importance for the patient in participating, as they can usually best assess whether a patient is eligible or not. At the moment, however, the ready knowledge about medical research among these healthcare providers is often not up-to-date. Doctors often do not know what colleagues are working on or which medical studies are being conducted in a hospital.
- **Patient organisation:** plays a key role in guiding the patient following the diagnosis and pointing out the potential medical research within the indication. Such an organisation can act as a source of information and a peer sounding board and, as a representative, can inform the patient about the options via its website, newsletter, meetings, etc.
- **(Research) nurses:** they often have the most contact with the patient in the treatment circuit and can guide the patient during a treatment process and, where possible, facilitate the conversations between doctor and patient.
- **Pharmacy:** the pharmacy is a central place to obtain information about medicines and treatments, both for patients and family members or possibly interested healthy study participants. The pharmacy can facilitate this information provision by means of its information boards or the active provision of brochures and information at the counter.

- **Patients with practical knowledge:** within each patient organisation or disease area, an overview should be provided of patients with practical knowledge who play a prominent role within their area and already have extensive experience in participating in medical research. They can share their experiences in talks or meetings with patients and refer them to the right places for information.

> ***"The work of those with practical knowledge should be more widely disseminated and marketed."***

- **Pharmaceutical companies:** like other sponsors of medical research, they can make a major contribution to the available information on such research by providing a layman's summary in a standard template when delivering the documentation.
- **Healthcare insurers:** they should provide clear information to policyholders regarding participation in medical research. Particularly in the area of the reimbursement of expenses (possibly pan-European for international medical research) and the possibilities for the patient to go abroad if suitable medical research is being conducted there.
- **The patient himself:** patients should be encouraged to take initiative and responsibility and should also be able to manage more of the process themselves.
- **CCMO and VWS:** central regulatory and legislative bodies such as CCMO and VWS [the Ministry of Health, Welfare and Sport] must provide for an accessible, independent and user-friendly register. In addition, they should provide for an adjustment of the legislation and regulations, where necessary, to optimise the process around medical research design and information provision (more use of compulsory fixed templates, mandatory use of layman's terms and a focus on patient-friendly use).

Added value of one central medical research register in the Netherlands

The majority of the interviewees clearly see the added value of a central register in the Netherlands, provided that one very clear condition is met: the information must (also) be made available in understandable language. Respondents see the added value of this because many people currently lack information. To avoid losing their support, patients should, however, be involved in the development and decisions (through patient panels, for example). In addition, it is important to involve the right experts in the construction of the register, such as for writing in comprehensible language and making the interface user-friendly. In addition, the register should not include *too much* information. It then becomes difficult to keep it up-to-date and easy to lose sight of the overall picture, which can put people off. What respondents considered especially positive is that this register is to be regulated by a central government body. This gives people confidence that they are consulting a reliable source. This link with the government gives weight to and a guarantee of factual information without any unclear conflicts of interest or sponsoring from the pharmaceutical industry.

On the other hand, there are also interviewees who do not immediately see the added value at this time. Indeed, there are diseases (within oncology, for example, or a disease like cystic fibrosis) where a professional patient organisation is well-organised in its information provision to patients about medical research. For them, there is currently no immediate need for a central register. They do not expect that

their patients will quickly consult an 'impersonal' register or actively seek participation opportunities there. However, these organisations are open to collaboration in the future: if, in time, there is an up-to-date register, they will see benefits for themselves in terms of efficiency, provided that they can click through to this source or refer to it from their own websites.

"Make sure you construct something that is actually aligned with what the target group wants and not just what the policymakers THINK we want!"

Above all, a new central register should have a direct added value for and a focus on providing information to the patients. After all, there is already the internationally highly regarded www.clinicaltrials.gov for professionals.

The following suggestions are made for optimising the central register. Ensure:

- A register in Dutch, with summaries in layman's terms
- A search function that has the capacity for extensive searching, also in layman's terms
- A logical structure and lay-out; involve the end user (patient) in this
- A 'share' function so that it is easy to share content with family or to store content and print for own reference. And/or to make a questionnaire for discussion with the attending physician
- An option to set up a personal profile in which one can indicate areas of interest, so that the user automatically receives notifications of new information in these areas of interest
- Regular mention of the register in patient organisation newsletters/websites
- Active communication of knowledge, especially to doctors
- Making use of the combination of '*experienced hands' + 'young creatives from outside'* in the construction of the register. In this way you combine extensive expertise with fresh new ideas for the rollout of a central register

"It is normal in every sector that users are able to assess products and services online for service and product improvement. Why not for studies in a central register?"

- A glossary/legend, so that the register remains readable for everyone
- More background information about the patient's rights and obligations, ethics, insurance for study participants, etc.
- Information about the quality of life, the burden on the patient, costs/expenses and/or reimbursements for the patient without only focusing on hard scientific figures
- A system that can guarantee the register will be kept up-to-date
- A responsible role for the patient organisations and letting them point their members in the direction of medical research and information in the register
- Adjustment of the term 'study subjects'. This puts people off and sounds negative to the patient and potential participants
- Doctors being aware of the registry. Train doctors to use it and ensure that they play a

key role in guiding the patient with information provision about medical research. In doing so, preferably follow the 'patient journey'. The 'old guard' patients often blindly trust the doctor's authority

- Involvement of people with practical knowledge so that what you construct is in line with the wishes of the target group
- Lots of icons, symbols and visualisations
- A depiction of (a link to) medical research results
- Information about stopping or rejecting medical research

Other suggestions

What almost unanimously emerged as a point for improvement is the 'aftercare' of study participants who have taken part in a medical study. What respondents said they currently miss is feedback from the research results to the study participant. Provide feedback to the study participants on the effect of their participation and express gratitude for their participation.

In addition, the interviewees believe that more basic knowledge about research should be offered to the general Dutch population, including how a medical study is set up. This would mean that people gain some knowledge about medical research *before* becoming a patient.

Furthermore, the wishes of the patient can be better taken into account in the design of medical research and the provision of information: "What's in it for *me* if I participate?" In that respect, there is a big gap between the goals of science (*long-term vision*) and the patient (*the here and now for me*). The cognitive ability of patients after a serious diagnosis is often not accurately interpreted. This needs to be taken into account more when the information is offered to the patient.

"The cognitive ability of patients after an intense diagnosis is often overestimated!"

We will also have to look at how the older population, in particular, can be reached. This is of great importance because there is increasing demand for sufficient participants in medical research in the 65+ and 75+ age categories. They make relatively little use of the internet, so offline materials should be generated. Or the focus could be on reaching the family or children of the elderly patient.

Finally, facilitate the interaction between the scientist, doctor and patient and ensure uniformity in questionnaires and procedures to increase efficiency and support.

5.3 Group discussion

Experience with medical research

The participants in the group discussion are all experts in providing information about medical research to patients and their relatives. They bring to the table years of experience from various angles: from pharmaceutical industry to UMC and from umbrella organisation to innovative researcher. There is a great deal of expertise, particularly from the field of oncology, both in the field of policymaking concerning the provision of information on medical research, and in the field of communication and interaction with patients in daily practice. There is also expertise about the technical and innovative aspects of providing information to patients.

View on current availability and accessibility of information about medical research in the Netherlands

The availability and accessibility are currently insufficient. When healthy people or patients read information they have looked up themselves about medical research, they have no idea whether they would fit into a specific study. Nor does the CCMO site have enough information about this. Many umbrella websites such as kanker.nl play an important role in the provision of information about medical research. In principle, all information (especially oncological) on medical research with patients can be found here. However, it often appears that this information is still too difficult to allow patients to assess whether they fall within the criteria of the research in their stage of disease. If information about the disease stage is easy to find, patients can better understand whether they are eligible for participation in a study.

The participants in the group discussion indicate that the process of including research information on kanker.nl, for example, is overly dependent on the search for ongoing research in different existing sources (CCMO register, clinicaltrials.gov, websites of various study groups) and whether or not study coordinators respond in time. In practice, the information from the various sources is not always up-to-date. If agreement is reached for publication, a patient-friendly text will be approved by a study coordinator by means of a statement and subsequently submitted to the METC (Medical Ethics Review Committee) for the purposes of information or for assessment.

We must assume that patients searching for information for the first time do not immediately know what exactly they are looking for. There is often little good information to be found or none at all. An information booklet can be provided, but people find it difficult to read it all the way through. However you present it, the material remains difficult.

A practitioner is an important link, and should also discuss the medical research with the patient. The practitioner and/or a research nurse can explain to the patient what he or she should expect in a study. This enables people to make a conscious and better choice about whether they want to participate in a medical study.

Even when patients have some experience in online searching for information about medical research, that information is regularly out of date. If a patient is looking for a last resort, this must be addressed

efficiently and it must be ensured that the correct and up-to-date information can be found on the websites and channels intended for this purpose. In that respect, there is still a lot to be gained from the current technical possibilities: At present, the number of registered parameters is simply insufficient (information about participating hospitals is particularly lacking). Information in patient-friendly language for every study should be stored covering the nature of the study and the most important criteria for participation. Incidentally, this is not to be found in the new European regulations.

The question is also whether people know what they are looking for. After all, there are also people who have never heard of medical research. So how do you ensure that people know that information about this research is available? There are a lot of (sub)websites; many places where we can find information. It is much better to have one central place where all related information can be found. That would make things a lot easier for patients and their practitioners. We would be better off having one good source instead of different places where information can be found. All agree that it is desirable to create one trial register for all patients.

The process involved in a study must also be examined further. How do we arrive at the information for patients and how do we present it up in a uniform way? How can new information be automatically updated or modified in a simple way?

There is enough information in the area of oncology, for example, but there is still much room for improvement. Confidence is both necessary and desirable for effective collaboration between organisations that use each other's data, and transparency is needed about the process of generating information about research (e.g., has/has not been reviewed by the METC). In the area of oncology, for example, everything is relatively well-organised and a lot of information is easy to find, but for other diseases patients are often very dependent on the doctor or specialist for help. Information about various medical studies must be readily available in one step, regardless of the disease.

Finding and providing information

Participants' experience in daily practice is that the new standardised study participant information form (PIF) is still not entirely as it should be. The purpose of the new PIF is to present concise and clear information in a limited number of pages. The limited space for information often leads researchers to refer to a number of attachments. The PIF is therefore not the right channel for publishing information for patients about medical research, nor do we want that because of the many changes that are involved. Patients at the UMC Utrecht were asked about the PIF and the information that is provided when starting a medical study. Patients find that there are too many pages of information and don't read it all. What the patient does want is information about all medical studies in which he or she can participate. One proposal from patients involved was to give a one-page summary per medical study, so that an initial selection can be made. The patient can then indicate what additional information is desired. The collaboration with METC/CCMO needs to be improved in this area: it is desirable to require a single uniform format for patient information in medical research, in Dutch. A short and succinct form with a concise description of the patient group, where the medical research is being carried out, who the doctors are, the duration of the research, as well as everything that is important for the patient, such as the burden involved. More customisation must therefore be offered to the patient.

If you really want to reach the patient effectively, then the language must match that of the patient. Verbal information is also of added value. A patient often prefers to have a conversation first, before reading the information. It is also important to provide information about medical research at various stages and to critically review what information is offered and when.

According to the participants, there should be a central information point about medical research for the patients. According to the participants, the CCMO should determine and record how that information should be provided. A summary would be very helpful in the preliminary phase. The CCMO can establish this nationwide and start collaborating with many other parties who already have experience in providing information about medical research.

In addition, respondents feel the new European regulations could be even more ambitious. The new regulations are mainly about providing patients with information concerning completed medical studies, but right now we are especially concerned with information about ongoing studies, too. While this information is publicly available, it is not currently stored in existing registers in patient-friendly language. In addition, information from registers can only be seen on their own website, and this is really a big problem. Many academic hospitals and even research organisations do not have an up-to-date overview of their own ongoing studies.

Added value of one central medical research register in the Netherlands

We are currently working on one new central register in the Netherlands. The desired information for the patient can be included here and this register is accessible to everyone. Everyone agrees that such a register is certainly of added value for the Netherlands! Ideally, this will be a register that contributes to: completeness, transparency, reliability and an automated process for obtaining all information.
We must work towards a website that is clear and transparent for all patients, in terms of both language and content. It can also be a secondary goal for practitioners to see what kind of research is being conducted nationally outside their own hospital.
A single database or register also means just one source that needs to be kept up-to-date, where everything is entered and available for both patient and healthcare provider. So at minimum, the central register must have an API (*application programming interface*), which ensures that the information on medical research can always be shown from the same source on hospital websites, websites of patient organisations and apps. The best scenario would be that the most important and regularly changing information from a study can be amended in a very simple way, preferably via an app (e.g., is a study open, who is the contact person, which hospitals are participating, etc.). This makes it much easier for researchers to keep research information up-to-date.

Ensure that the register is complete, that doctors can see the medical information in their digital pocket card and that patients only see the patient information on a patient website or portal. This central register can then also be the source for every hospital in the Netherlands of an up-to-date overview of all current medical studies within their own hospital. Of course, the items that should only be available for an METC should be protected.

The CCMO will, any case, have to consider what the patient needs (per target group or per disease) and

must also ensure that this information can also be provided. To this end, the use of basic texts, instructions and templates for delivery of the data is very important. We also need to work with more organisations. The participants already have valuable experiences and templates to serve as a starting point for a national roll-out. That often ensures more progress in the projects because you can start with something concrete. It is important to use basic texts and introduce uniform templates via a central control system as soon as possible. After all, building a register takes a while and this would mean that a relatively quick overview and structure is created. As soon as the register is finished, the right information can then be loaded relatively easily.

Other suggestions

The moment such a register exists and a patient is looking for a medical study in which he or she could participate, and it appears that the patient does not fully meet the criteria, it would be desirable to notify the patient as soon as there is a new study that does fit with what he or she is looking for. This is the case on kanker.nl, for example, and can easily be included from a technical point of view. The patient can create a personal profile, so that it includes everything relevant to that patient.

Consideration should also be given to the possibility of mentioning contact details of the researcher(s) in the register, and the publication of summaries and results of the research in understandable language. The items that are stored per study must, in any case, be 'dynamic'. It must be possible to remove or add parameters, make them mandatory or non-mandatory, etc. Many more methodological parameters should be recorded. These can then always be added if the 'back end' of the new register makes this possible. (This is not state-of-the-art technology.)

Finally, we must give patients the opportunity to contribute to determining all the information that must be offered to patients before, during and after a medical study. Everything must be understandable.

6. Recommendations

The above results confirm the impression of the DCRF Working Group Recruitment of Study Participants that patients rarely or never have knowledge about which studies are active or already completed ('ongoing medical research') and that, as a result, it is unclear to them whether there are any studies to which they might be able to contribute. The results also endorse the importance of improving this situation. There is a clear and strong desire among all participants in this research to improve the accessibility and comprehensibility of information about medical research. Here follows is a description of what is needed for this improvement according to patients and the others with (practical) experience who have been involved in this project.

The following recommendations have been formulated based on the information provided by the patients and various people with (practical) experience. The recommendations are subdivided into substantive recommendations, recommendations for communication about these outcomes and

recommendations for their implementation.

6.1 Substantive recommendations

I. Through which channels and information sources do potential study participants want to be (better) informed of the existence of (and possible participation in) active and recently completed medical studies, and what role can a central register/database play in this?

Information about medical research must be understandable and accessible to patients and the people around them. What all the participants in this study are waiting for is one central and reliable source of comprehensible information. This source of information must be accessible through various channels and also able to provide tailored information.

In addition to obtaining information about medical research via the treating physician, the internet appears to be by far the most widely used channel if the potential study participant is looking for information about medical research. It is therefore obvious that information should be offered online. People are currently visiting various websites and making extensive use of search engines. This implies that a wide range of sources are consulted. These sources are not always up-to-date. The organisations involved indicate that it is desirable to have one reliable source in the Netherlands, where all necessary information is up-to-date and on which other organisations/websites should be able to base the information they provide.

There is not one particular moment when people want information about medical research. Both the moment of diagnosis and during the treatment process are mentioned. It is therefore important that all the information that is provided is made up-to-date and comprehensible for the patient at various times. References should also be made to this information and where it can be found at various times during a treatment process.

As the results show, the healthcare provider in particular plays an important role in providing and pointing out the information about medical research. It is therefore essential that healthcare providers (doctors, pharmacists and nurses) be informed and remain informed about the range of medical research. A reliable, clear source of information is therefore required for healthcare providers and patients.

A central register is generally seen as having a great added value. However, in developing it several issues need to be taken into account if it is to offer real added value for patients:

- In each development step, involve at least a delegation of patients (for example a patient panel) so that the connection with the target group is guaranteed.
- Provide the information for patients in ‘layman’s terms’, at an understandable level for the average patient. Make use of the right expertise to handle this translation and have a delegation of patients regularly proofread or check randomly for readability.
- Use the substantive and procedural knowledge and experience that already exists at various institutions that already publish information for patients about medical research. Make use of this experience and collaborate to keep the data in the register up-to-date.

- Ensure that the information from the central register can also be used for information at other locations. For example, patients indicate that health foundations and patient organisations are logical places for them to seek information. Enable these organisations to share the information from the central register effectively and easily, while maintaining and managing a single source (the central register). In technical terms: enable the use of APIs (*application programming interfaces*).
- Create awareness and support: Make all parties involved and the target group aware of the arrival and the importance of the register and ensure that healthcare providers, researchers and patients continue to find their way to this register. Consider, for example, using the coverage of patient organisations (websites) and pharmacies (information wall) in campaigns.
- Keep in mind that the specific wishes of patients (patient groups) can differ materially per disease area. Consult and, therefore, preferably involve a wide range of those with (practical) experience from different areas of interest.

II. Where and using which terms do potential study participants currently search for information about medical studies?

People mainly search for the name of the disease. In addition, names of 'medications', 'doctors', 'hospitals' and 'treatments' are often mentioned. There is a wide variety of names people search for. To make the central register user-friendly, it is useful if it can be searched for using many different terms. Pay particular attention to different spellings, synonyms and the differences in (medical) names of disorders. The appendix with all the search terms mentioned (*Appendix 2*) can help with this.

People mainly search online for information, as mentioned above. In addition, many people (still) like reading information on paper. It was also underlined in the group discussion that patients like to receive information both verbally and on paper. The verbal contact and information on paper complement each other and provide a better understanding of the complex material.

III. What information should potential study participants be able to find in a central register in order to gain a first impression of the range of relevant medical studies in the Netherlands?

As a minimum, the information on medical research must consist of 1) the treatment being studied, 2) the hospitals where the research is taking place and 3) the possible benefits and risks both to personal health and finances.

From the experience of organisations that already share information on a website, we also know that people also request the results of research, the personal burden of participating in a study, inclusion and exclusion criteria, and contact details for more in-depth information provision. Thuisarts.nl is an example of a website with clear information in a fixed format, focused on the questions that patients have and always including the reference to the extensive NHG (*Nederlands Huisartsen Genootschap* [Dutch College of General Practitioners]) guidelines for more thorough information.

Ideally, the first time patients search for or receive information, they want to read a maximum of one page per study and only information about the studies for which they are eligible.

6.2 Communication recommendations

This report alone does not suffice to actually improve the information provision about medical research. In order to achieve the much desired improvement, all relevant organisations must firstly be informed about the outcomes of this report. The DCRF can play a central role here. Subsequently, these organisations must be asked how they can contribute to this change. The DCRF Working Group Recruitment of Study Participants can play a guiding role in this and call authorities to account regarding their responsibilities.

Share the results of this research with the clients and developers of the new register and ask them for a substantive response to this recommendation. Those constructing the new register can be helped by people who have participated in this research project and the DCRF can help in establishing the necessary contacts for collaboration. Many participants in this study are very willing to help, contribute ideas and share their experiences as well as methods they have already developed.

It goes without saying that all those who have contributed to this research will receive this report. They can use the substantive results themselves and share them with their adherents and/or colleagues. Feeding back these results to the participants is just as important as the feeding back of results from medical research to the participants who have taken part.

6.3 Implementation recommendations

Wait no longer, get started right away! Do this together with the people for whom the information is intended and with the people who already have experience in presenting this information. At present, every organisation is developing its own methods and procedure and the information is fragmented or not understandable. There is a large support base to improve this situation and many participants in this project are willing to share their knowledge and expertise. Take advantage of this and strike while the iron is hot!

The introduction of a national template for the collection of research information should be started as soon as possible. Make room for patient-oriented information in this template and fine-tune the structure of the template with the patients. The uniform collection of information about medical research creates an overview and recognisability while also facilitating good data migration when the register is ready.

Provide guidance, transparency and collaboration, so that there is one reliable, up-to-date source for comprehensible information about medical research. Invoke collaboration and working methods in one uniform format. This will ensure speed and collaboration.

7. Accountability and word of thanks

This research was carried out by Daphne Bloemkolk and Ruud Nieuwendaal. It was possible to carry out this research within a very short period of time thanks to the willingness of their employers, *De Hart & Vaatgroep*, *Hartstichting* and Celgene, to make time and resources available. The support of the DCRF secretariat, namely Debby Slagtand, was indispensable.

This research has reached a large number of patients, thanks to the energetic cooperation of all the patient organisations that were approached. They deserve many thanks for their cooperation, because this has allowed us to better reflect the voice of the patient. We are grateful to the individual experts for their time and willingness to share their experiences and ideas. Thanks to all these people we now have a clear picture, which was gradually strengthened during the research when we had new conversations.

It has become even clearer to us that something really has to change and that many patients and others with (practical) experience are willing to help. We sincerely hope that this extended hand is quickly grasped by the appropriate authorities who can help bring about the change. And we also expect that every successive step will be taken together with the patients and those with practical experience. They have a lot of knowledge which is currently being used insufficiently and which we can use to achieve our goal faster and better.