‘Sponsor Centric to Patient Centric framework:’

Improving patient recruitment & enhancing their involvement

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The benefits of involving patients (PI) in clinical research are increasingly being recognised

**WHY:**
- Improve ‘quality’ of the projects (sharper/better aligned targets, etc.)
- Increase technical & commercial success rate of medicine development
- Buy-in of patients leading to faster & broader acceptance of the results
- Increased awareness among patients leading to increased therapy compliance

**WHAT:**
- Inclusion of (trained) patient experts into the project teams
- Explicit and adequate consultation of patients in all stages of the clinical research

**HOW:**
- Many approaches are possible
- Investigators/medical doctors often still struggle with the ‘operationalisation’ of PI
There is limited, but increasing evidence available that quantifies the benefits of PI.
Involvement of patients in clinical research can be envisaged at various levels of intensity...

<table>
<thead>
<tr>
<th>Patient investigator/Expert patient</th>
<th>Participation level</th>
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<tbody>
<tr>
<td>- Driving force</td>
<td>(7)</td>
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<tr>
<td>- Co-researcher</td>
<td>(6)</td>
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<tr>
<td>- Participant</td>
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<td>- Reviewer</td>
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<td>- Advisor</td>
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<td>- Information provider</td>
<td>(2)</td>
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<td>- Research subject</td>
<td>(1)</td>
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<td>- None</td>
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....and could offer benefits in all stages of the projects
There are numerous roadblocks, of different nature:

1) Mental
2) Communication
3) Recruitment
4) Organisation
5) Reward
6) Legal
7) Administrative
8) Governance

However, to this date PI in clinical research has not been widely implemented
Roadblocks for effective patient involvement (1): Mental

- Implementation of broad and effective patient participation will drastically change the clinical research process as we know it.

- Introduction of these kinds of changes requires a change in attitude among all stakeholders, and a full commitment from all stakeholders to the proposed change (process) and its consequences.

- This is a big challenge, because across the health care sector there is still significant opposition and resistance to this change (mental roadblock).

- Thus, the necessity of this change (the ‘WHY’) needs to be re-iterated, and support to translate this to the local situation must be available.

- The change must be endorsed and actively supported by top management layers (in hospitals, etc).
Roadblocks for effective patient involvement (2): Communication

- Studies show that a lot of miscommunication takes place between patients and doctors/investigators.

- As a consequence, vital input from patients is missed, which reduces the quality and chance of success of (many) clinical research projects.

- Hence, there is a lot of improvement potential in this area, to which each stakeholder must contribute:
  - doctors/investigators have to learn to ask questions to patients in an open way without interference of their own expectations regarding the response; they need to overcome their fear of asking a question to a severely sick person*
  - patients often withhold information to doctors (and investigators) about what is important in quality of life for them; they need to communicate clearly & honestly.

* 'Shared decision making in adjuvant cancer treatment', Marleen Kunneman. PhD thesis 2016. See https://openaccess.leidenuniv.nl/handle/1887/38221
The need for (communication) training for patients who will participate in clinical research projects is widely recognized,

In addition, doctors/investigators who deal regularly with (expert) patients or patient groups need to be trained in communicative skills in order to approach, inform, consult and involve patients in an optimal way**

In The Netherlands, we (DCRF) are in the process of setting up (pilot) training sessions for ‘professionals’ on how to carry out a conversation with a patient in a way that is effective and compassionate at the same time.

The training has been developed by two psychologists and is called ‘Excellente Gespreksvoering’ (= conducting an excellent dialogue).

** Input Barbara Scheffer, MsC; psychologist & trainer
Intermezzo

An effective 2-way communication is and remains to be one of the most difficult issues in human interaction, as this video demonstrates...

https://www.youtube.com/watch?v=frMz9s3OLwY
Roadblocks for effective patient involvement (3): Recruitment

How to find and identify:

• the right patient expert
• for the right task
• at the right participation level
• at the right education level
• at the right time

How to organize patient participation?

How to ensure sufficient inclusion in trials?

What is needed (information, education, organisation and infrastructure, governance,...)
Roadblocks for effective patient involvement (4): Organisation

• How can we ensure a consistent work process? Information, education, 

• How to organise it? Good (ict) equipment, good governance

➤ Patient organisations/associations could (should!) play a vital role in facilitating patient participation in clinical research (training & providing the patient experts, align on the desired participation level, etc.)

➤ As such they would act as the ‘liaison’ and the formal entry points to the (other) stakeholders in the field

➤ This requires patient organisations to explicitly adopt this as a core task and that they are recognised, equipped (also financially) and professionalised to be able to carry out this task
An example of effective organisation of patient involvement:

The Dutch Parkinson’s Association Patient Partner Team (Feb 2018)

https://www.parkinson-vereniging.nl/
Successful support to clinical research in NL by the Dutch Parkinson’s Association; a few examples

- Annual meetings with the major academic research centers in The Netherlands
- Involvement in (the set-up of) a ‘Big Data’ project on (early) Parkinson’s disease
- Collaborating with investigators in a study on cost-effectiveness of specialized nursing interventions for patients with Parkinson’s disease
- Facilitating the recruitment of (a specific sub-set of) Parkinson patients for an upcoming CT (phase 2B)

https://www.parkinson-vereniging.nl/
**Roadblocks for effective patient involvement (5): Reward**

- In clinical research, the project teams are often multi-disciplinary and staffed with professionals from diverse background.

- The patients who are added to the team have usually not (yet) received professional training for this and don’t get any pay or reward. This damages their perceived status, and reduces their impact.

  - Establishing a consistent ‘Reward model’ will help professionalize the PI. In this model, expectations can/should be clearly defined upfront and patients need to take responsibilities (and be held accountable for their agreed contribution).

  - In this approach, their level of participation and their status will increase.

  - (More) training is essential for patients to prepare them for their role in projects.

  - These training courses could be included in the Reward model as an in-kind reward.
Active involvement of patients raises questions and concerns with respect to legal limitations, such as: look what is possible and use that

- **Liabilities** – to what extent can a participating patient be held liable for failures or mistakes

- **Privacy** – (how) does patient participation in medicines research conflict with privacy regulations

- **Codes of conduct** – (to what extent) does a more close collaboration between Pharma innovators and patient (organisations) conflict with current codes of conduct?
Roadblocks for effective patient involvement (7): Administrative hurdles

• Next to the previous, investigators experience also numerous other, mostly ‘administrative’ managing roadblocks

• They are seeking clarity and alignment on practical tools (e.g. insurance issues, financial rewarding, labor contracts) as well as on the overall workprocess

• In The Netherlands, representatives of academia, hospitals, CRO’s and innovative Pharma decided some 10 years ago to join forces, with the aim to tackle and align on these and other roadblocks hampering the clinical research process.

➢ This has led to the establishment of the DCRF (Dutch Clinical Research Foundation)
Dutch Clinical Research Foundation (DCRF)
Combining forces to optimize the circumstances for clinical research in the Netherlands
Clinical research / trials in NL

Clinical research & trials in various settings:

• Academic medical centers  
  (most investigator driven research)
• General top hospitals  
  (most pharma driven research)
• Specialised research centers  
  (f.e. Breast Cancer Research Group) (combined)
DCRF Work groups

Participation from adjoined umbrella organisations

• Education;
• Electronic Patient File (EPD);
• Recruiting subjects;
• Ethical Review;
• Local feasibility;
• Congress programme committee.
Patient is important stakeholder: DCRF patient group

Patient involvement is needed to improve results of clinical research and to accelerate inclusion.

Aims DCRF patient group:
• Patient is an equal partner in agenda setting, design, research; implementation, distribution,
• Information that is understandable for patients; with easy access,
• Doctors know about that information
• Needs and demands of patients are the start of every CT;
• Patient consultation before designing a CT→ co-creation;
• Education on co-creation of clinical research for both patients and investigators.
General results
*(but probably the most important ones...)*

- Improved common sense of medical research in The Netherlands
- Improved communication between parties involved
- Improved information about current and done research
- Improved co-operation between parties involved
Conclusions

• There are still many questions, concerns and issues to tackle in order to have adequate patient participation in clinical research widely implemented.
• It starts with the *belief* in the benefits of this concept, the willingness to be open to change the current way of working, and with open communication between key stakeholders.
• It needs shareholders who take their responsibility in putting the benefit of the patient in front.
• The medicines development process is a complex process requiring the involvement and contribution of many resources from many disciplines. Consequently, the identified roadblocks can not be solved/removed by individual persons or entities.
• Cross-disciplinary *collaboration* is therefore essential to come to real and widely supported improvements (→ the DCRF-approach).
• Good governance, particularly active, visible and consistent support from top management layers, is essential to realise structural and sustainable changes and a good collaboration from the top to the bottom of the organisation and the other way round.
Conclusions and recommendations: Ideal scenario
How to proceed?
Acknowledgements

- Rob Hagen (Coordinator Expert Patient group in the Dutch Parkinson’s Association)