



**BeyondRCT -2:
towards co-operative citizen science in food and health.
International Conference, Amsterdam
25-26 September 2018**

Executive Summary

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Quotes from participants

“Highly productive conference, lots of energy and willingness to share and collaborate. Very pleasant experience.”

“Timely, comprehensive overview that tackles the big ideas but also delves further into practical applications.”

“My highlight was the collaborative session on day 2 to really get together and start creating something.”

“Unique initiative, with patients as drivers. Where most people say patients/people should be leveraging the change, here it is actually being done!”

“This is the most exciting event at this moment in healthcare.”

COLOFON

This Executive Summary is a summary of the main outcomes of *BeyondRCT-2: towards Co-operative Citizen Science in Food and Health*. Amsterdam, 25-26 September 2018
BeyondRCT-2 is the sequel of BeyondRCT-1, celebrated in March 2016.

Organization

Stichting Mijn Data Onze Gezondheid (MD|OG – Foundation My Data Our Health)
With the help of key partners and sponsors (see full overview on last page)

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Introduction

BeyondRCT means going beyond the so-called golden standard for delivering biomedical evidence: the Randomized Controlled Trial. BeyondRCT aims to contribute to the broadening of the methodological research repertoire in health, and to deliver new golden research standards that fit different situations and conditions. BeyondRCT hence doesn't mean doing away with RCT's, but simply applying them at an appropriate moment. Citizen Science fills in a specific slot in that methodological repertoire. In all its diversity, it represents a huge untapped research potential with the promise to generate new research hypothesis, to accelerate product and therapy development, to empower patients and to individualize medicine – or health for that matter. Unlocking this potential also has a major impact on research methods, the use of digital resources and the design of matching data infrastructure and governance.

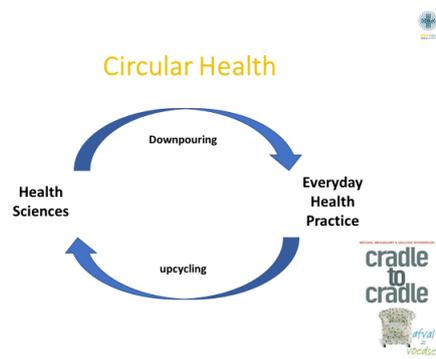
The 3 core themes of the congress were:

1. Approaches to data collection, data management and research by citizens in the health domain
2. New research methodology to extract wisdom from n-of-1 research and to upgrade it to collectively applicable knowledge, products and advice
3. The organization of a data infrastructure that allows data traffic between different sources, and that functions technically effectively and socially ethically.

The core purpose of the BeyondRCT-2 symposium was to produce a multiannual workprogramme Co-operative Citizen Science for the period 2019-2021.

The international BeyondRCT conference serves as a connecting node that inspires citizens, patients and professional experts of all kinds to jointly arrive at health solutions that fit the individual in the complexity of our common world.

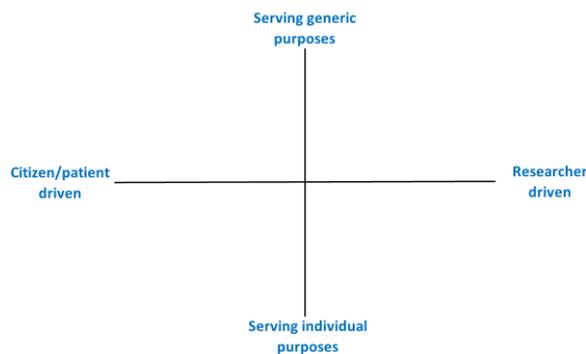
The second edition of BeyondRCT brought together over 100 attendants across disciplines, backgrounds and nationalities. Hosted in Circl, the ABN-AMRO meeting venue built on cradle-to-cradle circular economy principles, BeyondRCT-2 made clear that circularity in the health domain also exist. Traditionally knowledge and data go from science towards patients, but the reversed process is blocked, leading to an unintended accumulation of over-medication, ineffective spending of health care budget, an explosion of chronic diseases in the years to come and worst of all, poorly attended patients. Citizen Science promises to the close the loop, and to bring back real life data and knowledge from the work floor into health science and health practice.





Citizen Science is not a label to qualify a medical approach nor a therapy or product; Citizen Science can be labeled to any methodological effort to upcycle knowledge out of real world daily experiences. Citizen Science may take very different shapes and forms, depending on the gravity of either the lead in the citizen science project (citizen or researcher), and the purpose of the research

The potential of Citizen Science in Health



(geared towards individual or collective benefit and knowledge). There are quite a few examples of initiatives in the lower left and upper right quadrant in the above figure. The challenge and true potential of Co-operative Citizen Science, resides, however, in projects that integrate all four quadrants, serving both individual and collective purposes (going from n-of-one research to generic insights applicable in the public health knowledge body), and implying both citizens and scientists.

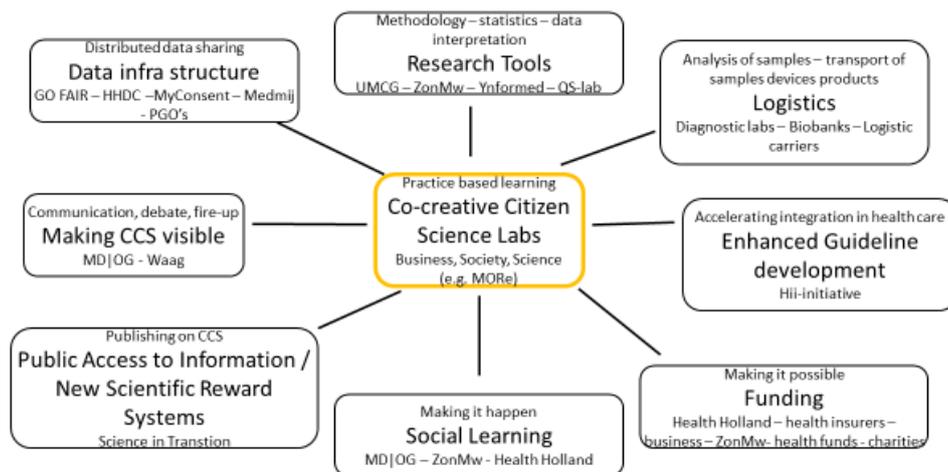
Core conclusions

After an inspiring and thought-provoking first day, a smaller group gathered at the historical Waag building to delve deeper, and to establish the ground for a work programme co-operative citizen science. Core conclusions of that session are:

- Citizen science is best served when developed around the carrier of a health urgency, be that a citizen already affected by a disease, or a healthy citizen with a worry about his or her health.
- There are plenty of health urgencies that are actively sought solution after by citizens, lots of ongoing patient-driven initiatives and loads of data already available and being collected.
- The resolution of relevant scientific and product development challenges (therapy, drugs, e-health devices) should be wrapped around these urgencies.
- There are plenty of interested researchers, companies and legislators that possess parts of the puzzle to make citizen science meaningfully and positively impact the health sector. Some of these puzzle pieces lead directly to the identification of a health urgency with a patient or citizen collective as a carrier.
- There is a screaming need for opportunities for citizens, scientists and companies to meet, learn and explore mutual interests and elaborate on the potential for collaboration.
- There is a need for concerted action to make co-operative citizen science work.

Envisioned key building blocks of a program on Co-operative Citizen Science (CCS)

Building blocks Co-operative Citizen Science (CCS)



- **Making the diversity of Citizen Science visible**

Over the past few years, there have been manifold expressions of citizens conducting research with their own and other people's data in the health domain. The conference showcased a few of them: kidney patients investigating a food-based approach to maintain health and reducing medication; cluster head patients putting their observations on the occurrence of symptoms related to their own interventions together in a web-based environment; patients with GIST (Gastro Intestinal Stromal Tumor) that exchange experiences through facebook with scientists performing a semantic analysis of their findings; a caretaker of an Alzheimer patient doing an n-of-one experiment with a food supplement. This is yet but the top of an iceberg. The manifestations of citizen research in health are very diverse and rich, span both well-known and prevalent as well as rare diseases, and also include Quantified Self initiatives. These need to be staged, honored and discussed in order to connect the right support structure to them and convert in truly learning co-operative citizen science labs.

- **Building appropriate ICT-infrastructure and Data Governance**

For Citizen Science to flourish, well connected information systems must exist, connecting both clinical data with non-clinical real world data, such as gathered in health apps and e-health devices. This demands personal health data lockers with API's that allow for connection, equipped with FAIR data points and in compliance with MedMij standards and



privacy regulation. To enhance citizen control over these data, consent is ideally organized through a citizen owned Health Data Co-operative. This solution would at the same time spur ethical secondary use of health data by researchers.

- **Developed adequate research approaches and statistical tools**

Beyond Randomized Controlled Trials, there is a whole world to win regarding research methodologies that explore highly contextualized and complex data, both qualitative and quantitative. These methodologies have validity on different points in the process towards building evidence, and in different contexts. Examples are n-of-one studies, Participatory Narrative Inquiry, Design Thinking and research, semantic analysis, etcetera. The use of eHealth and telemedicine devices adds potential to Citizen Science and poses additional methodological questions. The development of statistical tools that allow for drawing conclusions based on these data is a hot topic for mathematicians. Several research groups in The Netherlands and abroad are working on this. Disclosing both appropriate research methodologies and statistical tools for Citizen Science is crucial to strengthen the acceptance of Citizen Science among scientists, companies, regulators and the general public.

- **Create a routing from Co-operative Citizen Science to guideline development**

The findings that may come out of Citizen Research need to be incorporated in the guidelines for clinicians. However, in order to make it to these guidelines takes an enormous amount of money and time, as almost always RCT's are an obligatory hurdle to take. This money nor time is available, and the required RCT's are often in ethical contrast with the nature of Citizen Science. New routings for accelerated guideline development are currently being explored by the Hii Holland approach (Health innovation initiative of Health Holland) for non-drug medical innovations. Certain types of Citizen Science could be part of accelerating the process of guideline development, while at the same time Hii Holland approach could be inspirational for Citizen Science

- **Generate sustainable funding**

At present, the vast majority of funding for medical research is geared towards traditional approaches. Even though patient involvement is an obligatory element of most research nowadays, it has little or nothing to do with Citizen Science. Hence specific calls should be designed to meet this necessity. On the other hand, companies that wish to shorten their product innovation cycle, want to get quick feedback on their health products and therapies, and engage more directly with their clients, have a stake to win with Citizen Science. Third, insurers are among the first to benefit from Citizen Science, as their clients are equipped with tools that enable them to live a healthier live, and will hence reduce the collective health care expenditures.

- **Create public access to information and Open up Science**

The reward structure in Science, based on publications in peer-reviewed journals, is under debate. The critique is diverse. The most relevant one in relation to citizen science is that it tends to alienate researchers from the real why of their research, leading to publications for the sake of publication. Other issues are that it favors fundamental over applied research; it tempts researchers to publish preferably on 'sexy' or 'positive' topics; and so on. In general,



studies based on RCT's have a higher possibility of being accepted than studies that take n-of-one as a point of departure. Science in Transition is a Dutch scientific movement that supports a different attitude, also known as Open Knowledge. On the other hand, much of the scientific knowledge is not accessible for citizens as it is published in Journals that require expensive subscription rates. This should be changed in order to support Citizen Science.

- **Logistic infrastructure**

Citizen Science implies personalised delivery of equipment, devices, supplements, medical aids, food etcetera. This will only become more relevant as the trend is that health care will increasingly be based outside the formal health centers – at home. Specifically, citizen science often implies the analysis of body material (blood, tissue, feces etc). These comprise both quite standard parameters, but also not-so-regular biomarkers. At present, it is sometimes difficult for patients that want to test specific parameters to find an appropriate lab, or a facility with the right equipment to take the sample, store it well and transport it to a lab. Furthermore, there is no procedure available to facilitate long term storage in biobanks of body samples that emerges from citizen science. Taken together, Citizen Science holds a potential for logistic companies.

- **Develop co-creative citizen science labs**

The central building block consists of co-creative citizen science labs, in which citizens, scientists, companies, data-infra developers, regulators and other stakeholders collaborate in a learning-by-doing mode. These Co-operative Citizen Science Labs may be very different in nature, but have at the heart a health concern carried by one or more citizens / patients.

- **Social Learning for Co-operative Citizen Science**

For all people, from citizen and patient to professor, citizen science implies a major change that points to many obstacles that are not technical or logical, financial or legal. Instead, these obstacles are rooted in the human dynamics around science and health care: the patterns of collaboration, the views and modes of conduct of different stakeholders, the uneven distribution of expectations and resources, etcetera. Hence, even if we have more and more citizen science tooling, even if the scientific foundations grow, even if guidelines provide guidance and if there is funding available, then we must not forget to include all of those involved in the change, and keep a sharp eye on how stakeholders can be included and supported to make the change. Make sure that all involved are informed, motivated and mandated to contribute to and make use of the technical infrastructure.





Existing and potential co-creative citizen science labs

The following overview is by no means complete. Main purpose is to give a snapshot of the potential of co-operative citizen science labs present in The Netherlands.

MyCardio: patients challenge and test their own cardiovascular interventions

There are dozens of ways people with Cardio-vascular problems try to control their cardiovascular risk, while intending to reduce regular medication: vit K2, cholesterol lowering diets, exercise, specific supplements etcetera. Building a social and research infrastructure that facilitates their home-based experimentation greatly enhances the value of their data. A specific group are the carriers of ICD-devices. These devices emit continuously data, but these data cannot be plotted, as of yet, against daily health interventions. Hence, the potential of these data to support healthy lifestyle choices is not fulfilled. Lead: Mijn Data Onze Gezondheid

Cancer and food

The Dutch MoermanVereniging has a 6 decade-long history of documenting countless experiences of cancer patients that pursued food and lifestyle as a key aspect of their approach to healing. These documents constitute a very rich database for text analysis. At the same time, the MMV-community is a lively group of 6500 people, that in general are very dedicated to home experimentation and documentation with food therapy. As a group, they constitute a real world citizen science research group, whose efforts could be easily connected to modern data systems to allow real world interpretation of their achievements.

Cluster headache patients – Nobism

Nobism is an existing start-up initiated by a cluster headache patient. Nobism organizes a self-experimenting network of fellow patients that experiment with approaches to control their headaches and document symptoms. A basic ICT-infrastructure is ready. To make it more robust, investment and network is needed to strengthen compliance with data regulation and possible links with existing data cohorts for referencing with a wider group.

Personalised food delivery programmes for kidney -patients

Specialized food baskets are being developed for different target groups. However, the individual health impact of such food programme may differ, even when targeted to a specific diseases. Equipping such programmes with client-based aids for evaluation and monitoring, on parameters that are set by the client, will generate a lot of information, bot for the client as well as for the health



and food professionals. The BeterSchappen project, a start-up of kidney patient Edie van Breukelen, is an example of such a promising food delivery programme.

“I have a gut feeling”

Documenting the health intuitions of citizens may provide very relevant clues for research and product development – if appropriate methodology is available. This is the case of an initiative with Crohn Colitis patients, that makes use of Participatory Narrative Inquiry (PNI) methodology, an integration of qualitative and quantitative research. The Immunowell foundation, Hidden Health Solutions and StoryConnect are leading this development.

Professionals-as-citizens: taking work floor knowledge serious

Much of the nurses in the healthcare sector observe on a daily basis what works and what not. They are in close contact with their patients, and sometimes, born out of necessity, they experiment with approaches. They are citizen researchers in their own right, if it were not for the fact that there is hardly a system nor methodology available to document their insights. The Dutch company for medical aids, MediReva, is interested in approaches that deliver more value for their clients and the nurses, and that is able to document and to value the practical day-to-day observations of health practitioners.

Enhanced pharmacovigilance programmes

Pharmaceutical companies devise follow-up programmes to monitor side effects of their drugs. Their efforts could be greatly enhanced when linked to real world data gathered by the users of their drugs. Companies such as Abbvie are interested in exploring the potential of Citizen Science.

DiabetesM2 Data community

In the Netherlands about 1 million people suffer from Type 2 Diabetes. The current treatment in health care is treating the symptoms of the disease using all sorts of medication. Outcomes from various research projects show that lifestyle change may result in lower use of medication or even reverse the disease. This might sound as an easy approach but lifestyle change is not easy sustained by most patients. Within the diabetes type 2 health community, patients, scientists and companies develop methods to support sustainable lifestyle change in people with T2D. To this end, a DiabetesM2 data community is created that enables the development of eHealth approaches integrated with ethical access and use of personal health data. Patients/citizens control over their personal health data is deemed crucial. Such data is needed to create personalized lifestyle advices, both regarding nutrition and activity, that can be offered to patients. In fact a community controlled health data marketplace is needed. The T2D health data community will be developed as part of a TopSector Life Science & Health project. TNO leads this consortium with nine partners with an



important role for the Holland Health Data Co-operative and Castor (MyConsent) concerning the data sharing part.

Patient stories

The Dutch Foundation CCC has created a rich library of patient stories, documented by patient themselves and often published as books. These “ego-documents” reflect years of patient observation on health and health care, and constitute a rich resource for research. The collection is recently handed over to Erasmus Medical Centre, who also has committed to maintain and update the collection.

MyOwnResearch

The MyOwnResearch project is a project with two purposes. First, to deliver a proof-of-concept of a methodology that facilitates n-of-one research across the disease spectrum, and that at the same enables analysis of the aggregated data. Second, to apply this approach in the case of gut problems and fatigue in people with a chronic condition, delivering direct benefit for patients and new scientific hypothesis for researchers. The self-research by the patients is facilitated by providing microbiome and blood analysis, counseling with a General Practitioner to choose the most appropriate intervention (probiotics or a supplement), an app-based self-monitoring tool with personalised outcome measures, and a statistical analysis of the outcomes of the intervention. The project is a public private partnership, awarded with a grant by the Dutch Topsector Life Sciences & Health and the Collaborating Health Funds in the context of their joint *BeterGezond* programme aimed at generating innovative solutions for people with chronic diseases. Amsterdam UMC and Mijn Data Onze Gezondheid (MD|OG) are leading a consortium of 11 academic, business and civic partners.

The MyOwnResearch project kicked-off symbolically at BeyondRCT-2. Signatures were placed by Nico van Meeteren (Director Topsector Life Sciences & Health, Health Holland) and Hanneke Dessing



(Collaborating Health Funds, SGF) on behalf of the *BeterGezond* programme; on behalf of the MyOwnResearch consortium, Mat Daemen (chairman Research Council Amsterdam UMC), Anje te Velde (Amsterdam UMC, scientific co-lead MyOwnResearch) & Gaston Remmers (MD|OG, civic co-lead MyOwnResearch)



What is the next step?

The Secretary General of the Dutch Ministry of Health, Welfare and Sports, Erik Gerritsen, urged the participants on day one of the conference to collaborate and turn Co-operative Citizen Science into a success and a catalyst for health and health care.

Informed by the workshop on day two of the conference, there is a great need for time and space that allows for the gradual development of co-operative citizen science labs, in which the different building blocks can be aligned. Hence, there is a strong call for an entity to facilitate such process.

The process should include a number of tangible milestones. These potentially include:

- 2018-2020: A series of meet-ups around potential co-operative citizen science labs, specifically designed to engage the right stakeholders. Focus: project definition and elaboration.
- 2018-2020: A number of Citizen Science hackathons, in which citizens meet scientists to match their home-brew insights with those of scientists. Focus: create quick feedback loops between citizens and scientists, identify relevant leads for research and product development for scientists and companies, identify leads for larger project formulation.
- Spring 2019: Decisionmakers summit: round table with public and private funders in health. Focus: commitment to invest in Co-operative Citizen Science.
- Spring 2020: BeyondRCT-3. Focus showcase the achieved results. Identification of the next step.

These steps should be part of a vision to build a Co-operative Citizen Science Ecosystem, that will be fully blossoming within 5 years from now.

Foundation Mijndata Onze Gezondheid will take the lead in engaging conversations with partners that have expressed or will express interest to make such Co-operative Citizen Science Ecosystem come true. Both ZonMw (Dutch Funding Agency on Health Research) and Topsector Life Sciences & Health (Ministry of Economic Affairs) have extended an open invitation to kick-off this process.



Organization, keypartners and sponsors

Organization



Key partners



Sponsors

