DORP's Mission

Mission

Our mission is to become an established, sustainable organization which offers optimal professional support for investigator initiated clinical oncological research.
Our main goal is to improve clinical research by realizing a higher patient participation, less organizational hazards and an increasing number of studies. These should be performed in less time, have a well-defined scientific objective and the results should ultimately be implemented in treatment guidelines. DORP contributes to the design and conduct of high quality clinical trials.

Plan of Operation
To reach our goal, DORP collaborates with high-quality data centres offering complementary and well aligned services by means of in kind contribution of DORP employees to these centres in exchange for knowledge. In collaboration with the data centres, the knowledge will be used to set up best practices and remove organizational obstacles in order to improve investigated initiated clinical oncological research. An overview of all data centres and the services they provide is listed at our website.

The main services of DORP range from project management, statistical support and monitoring to patient involvement, but exclude actual data management. Apart from in kind contribution of DORP employees, financial resources can be provided to expert organisations (i.e. data centres) for recruiting staff which supports DORP approved studies.

Furthermore, DORP provides complementary services to clinical investigators such as a roadmap for trial procedures, a digital library with trial supporting documents, and a helpdesk for guiding (starting and experienced) investigators. DORP also mediates between investigators to assist with trial support at a local level. Simultaneously, DORP is building a clinical trial infrastructure for clinical research at a national level. DORP supports research groups in professionalizing their organization.

Key aspect of the collaboration with data centres and research groups is exchange and expansion of knowledge: DORP will benefit from existing best practices, will develop best practices when not available, and provide best practices where needed.

Partners of DORP

Research groups
DORP defines a research group on the following criteria:

- legal (& organizational) entity
- a (scientific) board representing all relevant disciplines involved in the tumour type of interest
- established an internal scientific review process according to predefined standard criteria
- the design and conduct of clinical trials as one of its main objectives

In total 16 active oncological research groups (figure 1) have been identified, who are in different stages of establishment and / or organisational maturity.
DORP will ask all research groups to submit project proposals for support.

	name
BOOG	Borstkanker Onderzoek Groep
DCCG	Dutch Colorectal Cancer Group
DCOG	Dutch Childhood Oncology Group
DGOG	Dutch Gyneacological Oncology Group
DHCG	Dutch Hepatocellular Carcinoma Group
DPCG	Dutch Pancreatic Cancer Group
DPOG	Dutch Pharmacology Oncology Group
DPOG	Dutch Peritoneal Oncology Group
DUCG	Dutch Upper GI Cancer Group
DUOS	Stichting Dutch Uro Oncology Studygroup
HOVON	Hemato-Oncologie voor Volwassenen Nederland
LWNO	Landelijke werkgroep Neuro-Oncologie
NVALT	Ned. Ver. Van Artsen voor Longziekten en Tuberculose
NWHHT	Nederlandse Werkgroep Hoofd-Hals Tumoren
WIN O	Werkgroep Immunotherapie NL voor Oncologie
DLCRG	Dutch Lung Cancer Research Group
DSG	Dutch Sarcoma Group
DTCG	Dutch Thyroid Cancer Group

Figure 1: Identified active oncological research groups by DORP

Data centres
DORP defines a data centre as a centre which has

- coverage of services at a national level
- experience in the oncological field
- services in trial preparation and /or trial conduct in one or more of the following: project management, data management, monitoring, statistics, patient participation. The data centre supports the (local) researcher (Principal Investigator) with its service.

DORP identifies the key data centres as presented in figure 2.

The services will be executed by the most dedicated data centre. DORP will collaborate with the data centres to discuss the required services and to follow up with the designation and allocation of the associated funds.

name	specialisation	location
NKI-AvL		Amsterdam
Radboudumc		Nijmegen
EMC		Rotterdam
MUMC		Maastricht
Maastro		Maastricht
LUMC		Leiden
IKNL		Utrecht
SKION	Childhood cancer	Utrecht
HOVON datacentre	Hemato-oncology	Rotterdam
BOOG studycentre	Breast cancer	Amsterdam

Figure 2: oncological data centres identified by DORP

Stakeholders and other oncological research related initiatives

Essential to reach its goals, DORP will also collaborate with stakeholders and other initiatives in some way involved in oncological research.

Stakeholders
DORP will closely collaborate with and give input to the Dutch Clinical Research Foundation (DCRF) working parties, thereby contributing to the implementation of national regulations and uniform documents as contract templates.
Next to the DCRF we are in close contact with:
- Patients (representative) organizations (as SPKS, Hematon ,BVN etcetera)
- Nederlandse Federatie van Kankerpatiënten
- Stichting Oncologische Samenwerking (SONCOS)
- Federatie van Medisch Specialisten (FMS)
- Nederlandse Federatie van Universitair Medische Centra (NFU)
- Nederlandse Vereniging van Ziekenhuizen (NVZ)
- Samenwerking Topklinische Ziekenhuizen (STZ)
- Hartwig Medical Foundation (HMF)
- Koningin Wilhelmina Fonds (KWF Kankerbestrijding)

Other initiatives in some way involved in oncological research.
A selection of these initiatives is mentioned below
- HEALTH-RI
- Data4lifesciences
- BBMRI biobanking
- Oncode

DORP Services

DORP provides two kinds of services, namely infrastructural and direct trial-related services.

A: infrastructural services

Category	Services
In General	- a dedicated help desk (a portal for all questions and requests for support) - a list of training/workshop courses related to aspects of clinical trials
Templates & Standardization	Providing (links to) templates for: - bylaws - board directives - organizational rules - CDA's - CTA's - Data transfer/-user agreements - GDPR rules and guidelines All in close alignment with the Data Centres and our external partners on a national level. DORP will stimulate initiatives where specific knowledge comes together.
Research environment	- Stimulating the research environment by lobbying and connecting to national initiatives relating to IGJ, DCRF, KWF, ZonMw, NFU and others - Publishing of new developments in the scope of conducting Investigator Initiated Clinical Trials - Advocating new and innovative trials in general
Monitoring, Project management and statistics	All pillars contain overall and transcending elements. Therefore DORP will actively improve these processes in order to facilitate the research environment.
Patient Participation	- Coordination of involvement by Cancer Patient Organizations (KPO) and creation of awareness in research groups on patient involvement in clinical trials - Embedding consultation of patient advocates in the study roadmap - Comprehensive trial information (during accrual and lay summaries of results) accessible for patients and lay public - Set up tools and procedures for patient involvement in investigator initiated studies, including general criteria for patient involvement - Develop training and organize training sessions for patient advocates and investigators

These services will be available for all cancer research group regardless of establishment or experience and / or organizational maturation.

B: Direct trial-related areas of services

The **focus of DORP** will be to support researchers/potential PI's to prepare for a study. We offer the potential PI dedicated services depending on their needs, only if complementary to services already provided by a data centre, or presence of a trial transcending element that will contribute to the overall research environment. In addition to the infrastructural needs we offer study specific services for the trials which DORP has selected.

Category	Services
Project management	DORP will offer extra support where needed in close tuning with the involved data centre(s) referring to logistic and organizational execution of the clinical trial. This extra hands-on support can be for example: - Advice on project documentation on completeness (explicitly not on scientific content) - Establish and make available all kinds of relevant templates (preferably standardised ones) - Provide and discuss a study roadmap - Provide a trial overview (risk assessment, critical path identification) - Provide flow charts and checklists - Support in planning of organizing a study team This way we will make optimal use of the knowledge and capacity of the data centres.
Statistics	- Strengthen statistical capacity (in volume and competencies) - Exploring development needs at current curriculum for clinical trial statistics - Creating network of qualified statisticians by: Virtual service desk (staffing) Participating in DSMBs, evaluation committees etc. Developing and sharing expertise in standardization and optimization Development of methodology - Design and analysis of new and existing trials - Efficiently (re)using clinical trial data for (translational) research
Monitoring	- Standardization of study specific risk-based monitoring methods and documents - Developing effective and (cost/resource) efficient cooperative models - Defining a monitoring plan - Executing (add-on) monitoring, to focus on critical elements in the study which will lead to improved guaranteed quality
Patient involvement	- Providing tools and procedures for the improvement and professionalisation of patient involvement - Tuning supply and demand together with NFK and KPO's
Others	Depending on the needs of the research group or PI, we acknowledge the need of help with funding and finances. Special needs will be discussed to determine the added value DORP can offer.

Financial provisions:

DORP services are financed through:

1) in kind contribution
2) temporary financial support for staff of data centre

Financial resources are provided to the data centre that is best equipped and available for the service needed, taking into consideration the preference of the PI. This will depend on the study and is therefore discussed per study.

Conditions for financial support:
In order to work towards sustainability of DORP, partners and/or data centres receive financial support under the condition that they deliver the following services:

- Provide requested support for study in question
- Create knowhow, methods and policies
- Work towards standardization of the specific topic
- Identify relevant transcending issues

Sustainability

DORP aims to improve its sustainability by co-funding of this initiative. Demonstrable results of DORP will contribute to the success of finding co-funders: due to its impact (socially, economically), clinical cancer research will no longer be a matter of debate. DORP will discuss with future co-funders in what way they may contribute to DORP.

Clinical oncological research groups or initiatives as well as funding parties should accept that DORP services are included as an integral part of the budget of research grants. Prior to this, relevant stakeholders (i.e. hospital organizations NVZ/STZ/NFU, Ministry of Health, healthcare insurance companies,) will be approached to secure a structural role of DORP in the national landscape of clinical oncological research. DORP will initially be developed as a support organization for investigator-initiated clinical oncological research. In the sustainability plan we will explore the potential cooperation with external partners.

Who will benefit?

DORP supports Investigator Initiated Clinical Trials that are executed by a research group. The supported trials will benefit directly from the services provided. DORP will stimulate individual researchers / potential investigators to join existing groups or to explore the founding of a new one.

Ultimately, the cancer patient will benefit, since more innovative well-conducted trials that are timely completed may result in earlier availability of practice-changing treatments and thus will improve the care for cancer patients.