

# The presentation will start soon



## This webinar will be recorded

Recordings can be made available for knowledge dissemination.



## Questions or remarks?

Join us at [www.slido.com](https://www.slido.com) and enter eventcode **datasharing** or scan the QR code. Or use the chat.



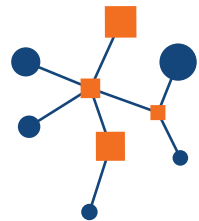
## Mute your microphone

Please mute your microphone to minimize background noise by clicking on the “mute”-symbol on the top of your screen.



## What can we improve for the future?

We are happy to hear any additional questions or feedback for our next expert meeting. Please contact us by mail: [robin.verjans@lygature.org](mailto:robin.verjans@lygature.org)



**BBMRI.nl**

*Health-RI partner*



**health RI**

*enabling data driven health*

# Virtual Expert Meeting Series: How to Make Health(care) Data Available for Research?

*12<sup>th</sup> of November 2020*

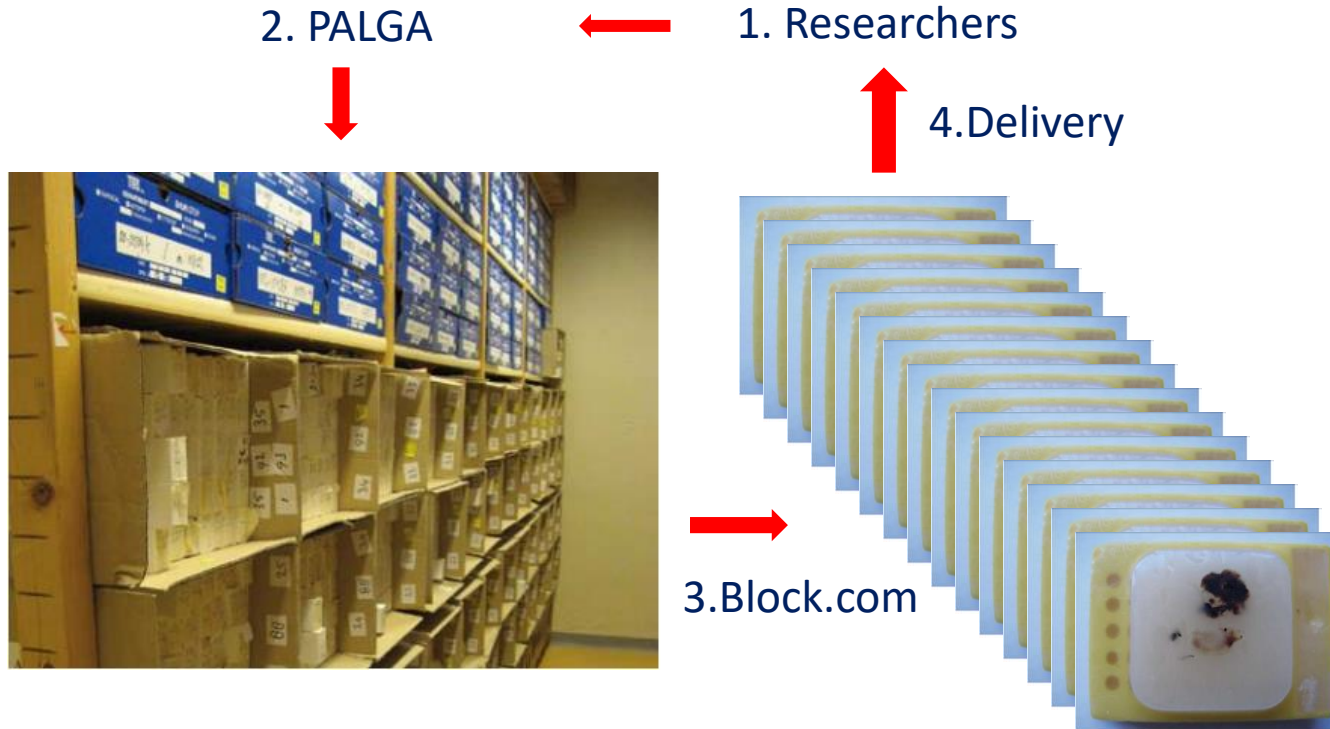
# BBMRI 2.0 Workprogramme 4

Linking registries and biobanks findable and accessible



# 2012-2015 BBMRI 1.0:

## A tissue block delivery service was the basis for the DNTP



## Met de service een applicatie (portal):

- The PALGA portal/DNTP tissue block services for researches gave insight in the block traffic.

| Aantal aanvragen:                             | 2017   | 2018   |
|-----------------------------------------------|--------|--------|
| Alleen verslagen                              | 5403   | 2410   |
| Alleen FFPE blokken                           | 8838   | 9069   |
| Alleen klinische gegevens                     | 6699   | 1730   |
| Verslagen en FFPE blokken                     | 3196   | 4475   |
| Verslagen, FFPE blokken en klinische gegevens | 4      | 2      |
| Verslagen en klinische gegevens               | 57     | 76     |
| FFPE blokken en klinische gegevens            | 0      | 117    |
|                                               |        |        |
| Totaal aantal lab verzoeken                   | 146    | 172    |
| Totaal aantal PA nrs                          | 24.163 | 17.874 |

## Tussen 2015-2019

- Consolideer de portal /DNTP met zgn. hub-medewerkers op 8 UMC's afd pathologie die services verleende aan laboratoria
- Bouw BBMRI 2.0 podium tool voor alle registries & biobanks



# BBMRI 2.0 → Health-RI

- **F**indeable
- **A**ccessible
- **I**nteroperable
- **R**euseable

# Virtual Expert Meetings Series

## Goal

- To create a **discussion platform** to discuss current hurdles, experiences and best practices how to make health(care) data available for scientific (re)use.

## Program

|   |                                                   |                                                                                              |
|---|---------------------------------------------------|----------------------------------------------------------------------------------------------|
| 1 | Thursday October 29 <sup>th</sup><br>14.00-15.00  | CBS - Fatima El Messlaki & Ivo Gorissen<br>NHR - Saskia Houterman                            |
| 2 | Thursday November 12 <sup>th</sup><br>14.00-15.00 | Durrer Center - Erik van Iperen & Wanda Hermans-Van Ast<br>IKNL - Peter Prinsen & Vincent Ho |
| 3 | Thursday November 26 <sup>th</sup><br>14.00-15.00 | LifeLines - Trynke de Jong<br>DataHub – Pascal Suppers                                       |

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# Request procedure

Erik van Iperen, datamanager IT

Wanda van Ast, manager

Netherlands Heart Institute/ Durrer Center



[Home](#)

[For professionals](#)

[For patients](#)

[News](#)

[About us](#)

[Contact](#)

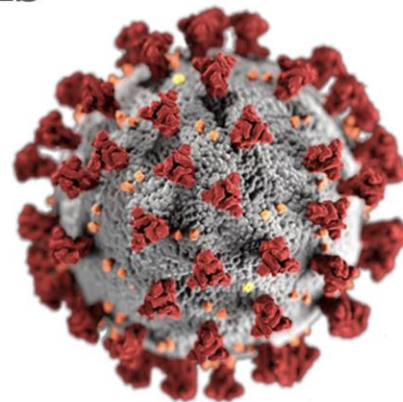
 [Nederlands](#)

# Registry of patients with COVID-19 including cardiovascular risk and complications

CAPACITY is a registry of patients with COVID-19 and has been established to answer questions on the role of cardiovascular disease in this pandemic. It is an extension of the Case Record Form (CRF) that was released by the ISARIC (International Severe Acute Respiratory and Emerging Infection Consortium) and WHO (World Health Organisation) in response to the emerging outbreak of COVID-19.

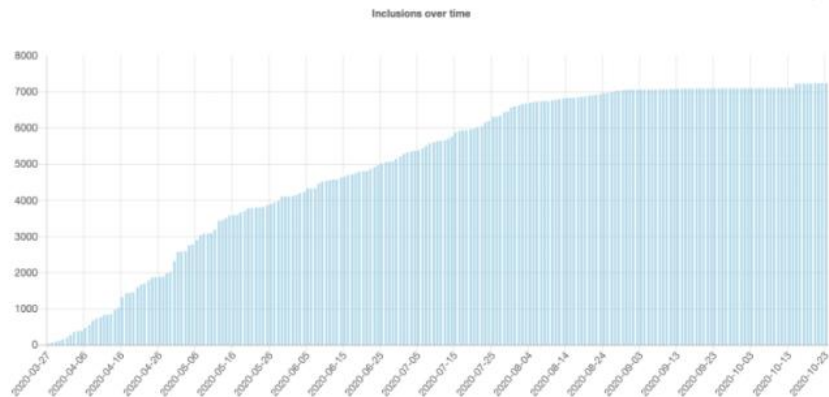
The aim of CAPACITY is to collect data regarding the cardiovascular history, diagnostic information and occurrence of cardiovascular complications in COVID-19 patients. By collecting this information in a standardized manner, CAPACITY can aid in providing more insight in (1) the incidence of cardiovascular complications in patients with COVID-19, and (2) the vulnerability and clinical course of COVID-19 in patients with an underlying cardiovascular disease.

Does your center want to participate? Join us! Please see our [infographic](#) on which steps you have to take.



# Design of CAPACITY

- Case Record Form of ISARIC (WHO)
- Additional instruments:
  - cardiovascular history
  - diagnostic information
  - occurrence of cardiovascular complications in COVID-19 patients
- Aim to provide insight in:
  - (1) the establishment and incidence of cardiovascular complications in patients with COVID-19, and
  - (2) the vulnerability and clinical course of COVID-19 in patients with an underlying cardiovascular disease.



**7321**

Total number of inclusions

**6643**

Total number of patients with  
follow-up

**75**

Total number of centres  
currently including

**13**

Total number of countries  
currently including

# Governance

- Complex project – two weeks to organise
- Review by METC: 24 hrs!
- Informed consent: opt-out for limited period of time
- Coordinating center: UMC Utrecht



Dutch  
CardioVascular  
Alliance

# Delivery of data from centers to coordinating center

Each  
participating  
center



Coordinating  
center



CAPACITY  
Cardiac complications in Patients with SARS  
Corona virus 2 regisTrY (CAPACITY)  
Version 2.0 May 2020



*Research protocol:*  
appoint local  
coordinator +  
involved  
researchers



Signed DTA by legal  
representative of  
hospital



**CAPACITY REGISTRY**  
Policy for Access to and Sharing of Data

**1. Introduction**  
CAPACITY is a Registry of patients with COVID-19 across Europe and has been established to answer questions on the role of cardiovascular disease in this pandemic. It is an extension of the Case Record Form (CRF) that was released by ICMAC (International Society Acute Respiratory and Emerging Infection Consortium) and WHO (World Health Organization) in response to the emerging outbreak of COVID-19 (<https://www.who.int/publications-detail/1>).  
The aim of CAPACITY is to collect data regarding the cardiovascular history, diagnostic information and occurrence of cardiovascular complications in COVID-19 patients. By collecting this information in a standardized manner, CAPACITY can aid in providing more insight in (1) the incidence of cardiovascular complications in patients with COVID-19, and (2) the vulnerability and clinical course of COVID-19 in patients with an underlying cardiovascular disease.

Confirm  
agreement with  
*Data Access Policy*



# Data access

- Data Access Policy
- Data Access Committee
- Data Access Procedure
  
- Check for overlapping proposals (see site)

[Participate](#)[Design and  
rationale of this  
registry](#)[Study  
documents  
\(global\)](#)[Study  
documents UK  
specific](#)[Participating  
centres](#)[Approved research  
projects and Data  
access](#)

Together we are investigating the role cardiovascular disease in the COVID-19 pandemic. We sincerely invite our international colleagues and researchers to apply for data access or to join efforts that are already ongoing. The following six research questions have formulated by the Data Access Committee and are being assessed:

1. What is the incidence and pattern of cardiovascular complications in patients with COVID-19?
2. Does the clinical presentation of COVID-19 differ between patients with and without a history of cardiovascular disease?
3. What is the extent of cardiac damage in patients with COVID-19?
4. Do patients with COVID-19 and cardiovascular risk factors or underlying cardiovascular disease have a worse disease course? If this is the case, which cardiovascular risk factors and types of cardiovascular diseases are especially associated with a poor outcome?
5. Does the use of medication that influence ACE-2 expression worsen the course of COVID-19 (ACEi, ARBs, NSAIDs and thiazolidinediones)?
6. What is the effect of therapy for COVID-19 on patients with cardiac complications or underlying cardiovascular disease? E.g. chloroquine and effect on QT-interval.

**The following requests for data access have been approved:**

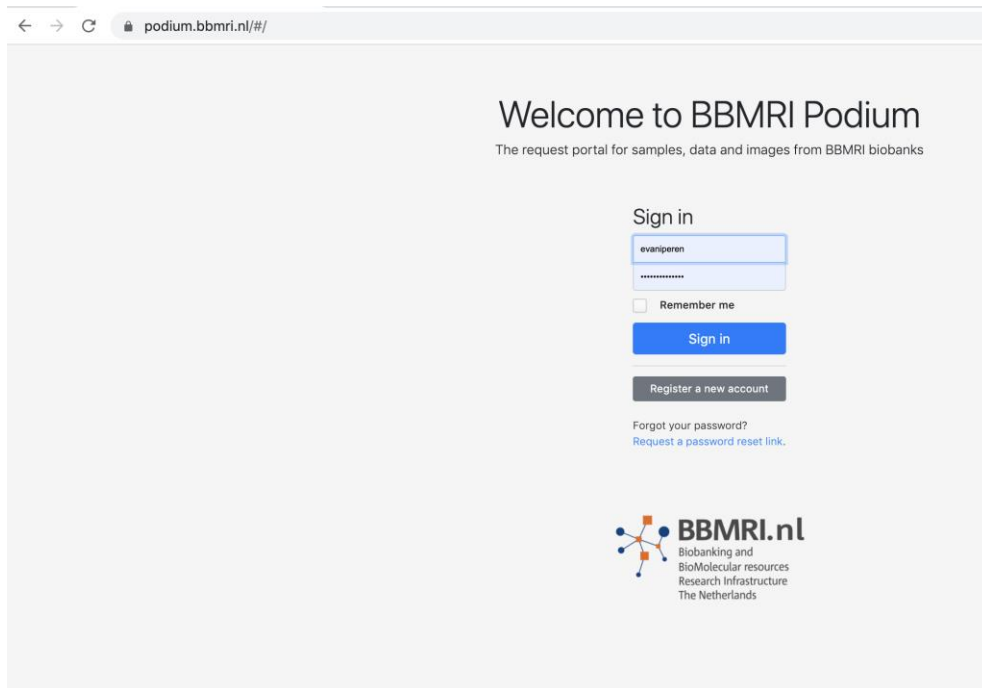
1. Oral anticoagulation and COVID-19 outcome – Disease modifiers
2. Sex differences in COVID-19
3. Effect of diabetes on COVID-19 cardiovascular complications
4. Acute cardiac injury and ACS in COVID-19
5. Arrhythmias and conduction disorders in COVID-19
6. Non-invasive 12-lead ECG analysis in patients with COVID-19
7. Disease-specific ECG features in patients with COVID-19

[Contact us](#) to join already ongoing projects

**How to apply for data access:**

- First check the overview of applications to avoid overlap with an existing project.
- Start your application by filling in the application form via <https://podium.bbmri.nl>. By sending this form the request will go to [info@capacity-covid.eu](mailto:info@capacity-covid.eu)
- To gain access, this form including your research questions, required data and/or samples, financing, and timeline of the research must be submitted
- Make your data selection using [this specific CAPACITY REDCap codebook](#). Please select your variables with corresponding variable names and labels. This file must be submitted as well alongside the application form using <https://podium.bbmri.nl>.
- The submitted application will be reviewed within one week by the CAPACITY Data Access Committee.
- Once an application is approved, CAPACITY will prepare a Data Transfer Agreement (DTA) for you to sign.
- Data will be released after signing the DTA.
- The data will be released in a digital research environment (the CAPACITY workspace).
- For further information regarding data access [see this file](#).

# Login/Register in Podium



A screenshot of a web browser showing the BBMRI Podium login and registration page. The browser's address bar displays 'podium.bbmri.nl/#/'. The page has a light gray background. At the top, it says 'Welcome to BBMRI Podium' followed by the subtitle 'The request portal for samples, data and images from BBMRI biobanks'. In the center, there is a 'Sign in' section with a text input field containing 'evanipere', a password field with masked characters, a 'Remember me' checkbox, a blue 'Sign in' button, and a gray 'Register a new account' button. Below this, there is a link for 'Forgot your password?' and a blue link to 'Request a password reset link.'. At the bottom, the BBMRI.nl logo is displayed with the text 'Biobanking and BioMolecular resources Research Infrastructure The Netherlands'.

← → ↻ podium.bbmri.nl/#/

## Welcome to BBMRI Podium

The request portal for samples, data and images from BBMRI biobanks

### Sign in

evanipere

\*\*\*\*\*

☐ Remember me

Sign in

Register a new account

Forgot your password?  
[Request a password reset link.](#)

 **BBMRI.nl**  
Biobanking and  
BioMolecular resources  
Research Infrastructure  
The Netherlands

# Create a new request

← → ↻ podium.bbmri.nl/#requests/new 🔑 🔍 ☆ ⓘ ⚙️ 🔌 🌐

BBMRI Request Portal Podium My Requests My Reviews Organisation ⌵ BBMRI 👤

## New Request

**Title**

Title of your research

**Request Details**

**Request Type(s)\* ⓘ**

☒ Data  
☒ Images  
☒ Material

\* Changing this value will clear organisation selection.

**Organisation(s) ⓘ**

BBMRI Metabolomics Consortium  
CAPACITY COVID  
CVON-CONTRAST  
Pathologie Amsterdam UMC  
Erasmus MC

**Linked Request ⓘ**

☐ Yes ☒ No

**Search Criteria**

eg. DNA samples from male patients >50 year with Prostate Cancer

## Research Proposal ⓘ

### Background

Your research background description

### Research Question(s)

Your research question(s)

### Hypothesis / Goals

Your research hypothesis and / or goals

### Methods

Your research methods that will be applied to answer proposed research question

### Related Request Number

Relates to request with number...

## Principal Investigator Details

**Name**

Name of the principal investigator

**Email**

Email of the principal investigator

**Function**

Function of the principal investigator

**Affiliation**

Affiliation of the principal investigator

## Attachments

Drag here or **browse** to upload.

| Name | Type | Uploader | Size | Upload Date |
|------|------|----------|------|-------------|
|------|------|----------|------|-------------|

Reset

Save draft

Submit

# Codebook



CAPACITY | REDCap

05/05/2020, 16:48

## CAPACITY

[Project Home](#) [Project Setup](#) [Online Designer](#) [Data Dictionary](#) [Codebook](#)

### Data Dictionary Codebook

05-05-2020 16:33

[^ Collapse all instruments](#)

| #                                                                                                                                                                 | Variable / Field Name                                   | Field Label<br><i>Field Note</i>                                         | Field Attributes (Field Type, Validation, Choices, Calculations, etc.)                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|--------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Instrument: <b>ISARIC/CAPACITY - Participant Identification Number Pin (REQUIRED)</b> (participant_identification_number_pin_required) <a href="#">^ Collapse</a> |                                                         |                                                                          |                                                                                                                                                                                                                                  |
| 1                                                                                                                                                                 | subjid                                                  | Participant Identification Number (PIN):<br><i>999-9999 (SiteNo-PIN)</i> | text                                                                                                                                                                                                                             |
| 2                                                                                                                                                                 | studyid                                                 | Please contact your local study coordinator for the STUDY ID.            | descriptive                                                                                                                                                                                                                      |
| 3                                                                                                                                                                 | datecreated                                             |                                                                          | text (date_dmy)<br>Field Annotation: @TODAY @HIDDEN                                                                                                                                                                              |
| 4                                                                                                                                                                 | participant_identification_number_pin_required_complete | Section Header: <i>Form Status</i><br>Complete?                          | dropdown<br>0 Incomplete<br>1 Unverified<br>2 Complete                                                                                                                                                                           |
| Instrument: <b>ISARIC/CAPACITY - Inclusion Criteria (REQUIRED)</b> (inclusion_criteria_required) <a href="#">^ Collapse</a>                                       |                                                         |                                                                          |                                                                                                                                                                                                                                  |
| 5                                                                                                                                                                 | dsstdat                                                 | Date of Enrollment<br><i>dd-mm-yyyy; definition: date of data entry</i>  | text (date_dmy), Required                                                                                                                                                                                                        |
| 6                                                                                                                                                                 | sitenam_nhr                                             | Site name                                                                | dropdown<br>31 Admiraal de Ruyter Ziekenhuis<br>22 Albert Schweitzer Ziekenhuis<br>32 Alrijne ziekenhuis<br>11 Amphia Ziekenhuis<br>3 Amsterdam UMC, locatie AMC<br>4 Amsterdam UMC, locatie VU<br>33 Antonius Ziekenhuis, Sneek |

# Request overview organisation

BBMRI Request Portal Podium

My Requests Organisation Wanda

All requests 26

REVIEW

In validation 0

In revision 4

In review 2

APPROVED

Approved 16

DELIVERY

In delivery 0

CLOSED

Partially delivered 0

Delivered 0

Rejected 4

Cancelled 1

Organisation requests

| Request id | Title                                              | Request type(s) | Organisation(s) | Requester | Principal investigator | Date created      |                         |
|------------|----------------------------------------------------|-----------------|-----------------|-----------|------------------------|-------------------|-------------------------|
| 1973       | Arrhythmias and conduction disorders in COVID-19   | Data            | CAPACITY COVID  |           |                        | 23-10-2020, 15:58 | <a href="#">Details</a> |
| 1945       |                                                    | Data            | CAPACITY COVID  |           |                        | 10-10-2020, 03:03 | <a href="#">Details</a> |
| 1936       |                                                    | Data            | CAPACITY COVID  |           |                        | 26-09-2020, 11:18 | <a href="#">Details</a> |
| 1910       |                                                    | Data            | CAPACITY COVID  |           |                        | 31-07-2020, 08:51 | <a href="#">Details</a> |
| 1891       |                                                    | Data            | CAPACITY COVID  |           |                        | 26-06-2020, 11:18 | <a href="#">Details</a> |
| 1865       |                                                    | Data            | CAPACITY COVID  |           |                        | 15-05-2020, 17:07 | <a href="#">Details</a> |
| 1855       | The Impact of Anticoagulation Therapy with COVID19 | Data            | CAPACITY COVID  |           |                        | 10-05-2020, 23:58 | <a href="#">Details</a> |
| 1853       | Oral anticoagulation and outcome of COVID-19       | Data            | CAPACITY COVID  |           |                        | 04-05-2020, 12:20 | <a href="#">Details</a> |
| 1851       | Diabetes on COVID-19 cardiovascular complications  | Data            | CAPACITY COVID  |           |                        | 29-04-2020, 09:52 | <a href="#">Details</a> |

# 2 step validation

## Request 2002 to Durrer Center



Details [Attachments \(0\)](#)

**Title**  
DNA van COVID19 patienten met CVD

**Organisation**  
Durrer center

**Request Types**  
• Data

**Linked Request**  
No

**Search Criteria**  
DNA van COVID19 patienten met CVD

**Background**  
DNA van COVID19 patienten met CVD

**Research Question(s)**  
DNA van COVID19 patienten met CVD

☐ I hereby validate this request. Upon sending for review all organisation reviewers will be notified.

Reject

[Request revision](#)

[Send for review](#)

### Principal Investigator

erik van iperen  
erikvanpeer@gmail.com  
r  
f

Your request is currently waiting for validation by the organisation coordinator.

☐ I hereby validate this request. Upon sending for review all organisation reviewers will be notified.

Reject

[Request revision](#)

[Send for review](#)

# Request details including review comments

Request 1790 to CAPACITY COVID

1

DRAFT

2

VALIDATION

3

REVIEW

4

APPROVED

5

DELIVERY

6

FINISHED

Details
Attachments (0)

Title

Organisation
Capacity coord

Request Types

- Data

Linked Request
No

Search Criteria
1, 2, 6, 9, 14-24, 30, 40-108,118-175, 179, 185-250, 443, 450-451, 453-454, 457, 488-478, 481-486, 499-501, 509-584, 719, 734-735, 752-823.

Background
The protective and antiviral roles of these agents have not been studied thoroughly in the particular case of novel viruses such as COVID-19, and that requires further and prompt investigation at the current time. The exact mechanism of the

Hypothesis

Methods

Relative Request Number

Principal Investigator

Review

| Name | Date                | Result   | Comment                                                                                                                                                                                                                                                                                                                                            |
|------|---------------------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|      | 4/20/2020, 10:12 AM | None     |                                                                                                                                                                                                                                                                                                                                                    |
|      | 4/20/2020, 10:12 AM | Approved | needs besproken in DAC                                                                                                                                                                                                                                                                                                                             |
|      | 4/20/2020, 10:12 AM | Approved | feasibility we need to establish a pharmacology working group to discuss statistical power, methodologies to harmonize across different drug questions and prevent overlap. I asked Ralf Greenwald from LUMC to join                                                                                                                               |
|      | 4/20/2020, 10:12 AM | Comment  | High risk study needs more clear goals This study seems way too broad, looking at many different treatments and many different outcomes. My advice is to make the study more targeted on one or a few specific treatment and outcomes to avoid statistical significance fishing expeditions. Needs adequate confounding control for each question. |
|      | 4/20/2020, 10:12 AM | None     |                                                                                                                                                                                                                                                                                                                                                    |
|      | 4/20/2020, 10:12 AM | Approved | valt onder hoofdonderzoeksvraag relevant, maar overlap met 1773, samenwerking adviseren                                                                                                                                                                                                                                                            |
|      | 4/20/2020, 10:12 AM | Approved | Effect of selected medications on health outcomes Currently three proposals to study the effects of specific medications on disease outcome of COVID-19 have been proposed. Please seek cooperation.                                                                                                                                               |
|      | 4/20/2020, 10:12 AM | Approved | approve                                                                                                                                                                                                                                                                                                                                            |
|      | 4/20/2020, 10:12 AM | Approved | brode scope                                                                                                                                                                                                                                                                                                                                        |
|      | 4/20/2020, 10:12 AM | Comment  | Medication and COVID19 Retrospective analysis of various drugs on outcome. High risk of confounding by indication. Difficult to correct for differences in baseline characteristics. Will be part of the main paper investigating prediction of adverse outcome in COVID19                                                                         |

Reject
Request revision
Approve

# Review by Data Access Committee

1. Discuss submitted requests and review comments
2. Look for overlap with approved projects
3. Evaluation of data request
  - Approve
  - Reject (data not available)
  - Adjust (data partly not available / overlapping question, suggest to cooperate with other researchgroup)

# Based on DAC meeting: decision

Request 1790 to CAPACITY COVID

START

VALIDATION

REVIEW

APPROVED

DELIVERY

FINISHED

Details

Attachments (1)

Title

Organisation

Capacity covid

Request Types

Data

Linked Request

No

Search Criteria

1, 4, 40, 40, 108, 116, 178, 179, 185-250, 443, 450-451, 453-454, 457, 468-478, 481-486, 499-501, 509-584, 719, 734-735, 752-823.

Background

The protective and antiviral roles of these agents have not been studied thoroughly in the particular case of novel viruses such as COVID-19, and that requires further and prompt investigation at the current time. The exact mechanism of the

Hypothesis

Methods

Resubmit Request Number

Principal Investigator

Review

| Name | Date                | Result   | Comment                                                                                                                                                                                                                                                                                                                                            |
|------|---------------------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|      | 4/20/2020, 10:12 AM | None     |                                                                                                                                                                                                                                                                                                                                                    |
|      | 4/20/2020, 10:12 AM | Approved | reads broken in DAC                                                                                                                                                                                                                                                                                                                                |
|      | 4/20/2020, 10:12 AM | Approved | feasibility we need to establish a pharmacology working group to discuss statistical power, methodologies to harmonize across different drug questions and prevent overlap. I asked Rolf Greenwald from LONC to join                                                                                                                               |
|      | 4/20/2020, 10:12 AM | Rejected | High risk study needs more clear goals This study seems way too broad, looking at many different treatments and many different outcomes. My advice is to make the study more targeted on one or a few specific treatment and outcomes to avoid statistical significance fishing expeditions. Needs adequate confounding control for each question. |
|      | 4/20/2020, 10:12 AM | None     |                                                                                                                                                                                                                                                                                                                                                    |

Reject

Request revision

Approve

4/20/2020, 10:12 AM

Rejected

Medication and COVID19 Retrospective analysis of various drugs on outcome. High risk of confounding by indication. Difficult to correct for differences in baseline characteristics. Will be part of the main paper investigating prediction of adverse outcome in COVID19

Reject

Request revision

Approve

# Release data: start delivery process

Request 1788 to CAPACITY COVID

1

DRAFT

2

VALIDATION

3

REVIEW

4

APPROVED

5

DELIVERY

6

FINISHED

Details

Attachments (0)

Title

Organisation

Capacity covid

Request Types

- Data

Linked Request

No

Search Criteria

All patients with "Discharge" item completed in the CAPACITY-COVID Registry % of patients per site being treated with chloroquine Mortality per site (including palliative discharge)

Background

Research Question(s)

Hypothesis

Methods

Related Request Number

Principal Investigator

Review

| Name | Date               | Result   | Comment                                                                                                                                                                                                                   |
|------|--------------------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|      | 4/18/2020, 7:46 PM | Approved | OK, but revise hypothesis. Important topic, but the hypothesis as formulated in the present application is not adequate. This may introduce difficulties in comparing with other applications.                            |
|      | 4/18/2020, 7:46 PM | Approved | sluit aan bij reeds toegekend project 6 What is the effect of therapy for COVID-19 on patients with cardiac complications or underlying cardiovascular disease?                                                           |
|      | 4/18/2020, 7:46 PM | Approved | feasibility we need to establish a pharmacology working group to discuss statistical power, methodologies to harmonize across different drug questions and prevent overlap.                                               |
|      | 4/18/2020, 7:46 PM | Approved | Sample size Sample size requirement not explicated, thus cannot be reviewed                                                                                                                                               |
|      | 4/18/2020, 7:46 PM | None     |                                                                                                                                                                                                                           |
|      | 4/18/2020, 7:46 PM | Approved | valt onder onderzoeksvraag 6 relevante vraag                                                                                                                                                                              |
|      | 4/18/2020, 7:46 PM | Approved | Effect on mortality in COVID19 Observational study to evaluate the effect the effect mortality in COVID19 infected patients. Seek advanced statistical/epidemiological advice to adress drawbacks of observational study. |
|      | 4/18/2020, 7:46 PM | Approved | approve                                                                                                                                                                                                                   |
|      | 4/18/2020, 7:46 PM | None     |                                                                                                                                                                                                                           |
|      | 4/18/2020, 7:46 PM | None     |                                                                                                                                                                                                                           |

Close request

Start delivery process

# Release of data

## Request 2002 to Durrer Center



Details [Attachments \(0\)](#)

**Title**  
DNA van COVID19 patienten met CVD

**Organisation**  
Durrer center

**Request Types**

- Data

**Linked Request**  
No

**Search Criteria**  
DNA van COVID19 patienten met CVD

**Background**  
DNA van COVID19 patienten met CVD

**Research Question(s)**  
DNA van COVID19 patienten met CVD

**Hypothesis**  
DNA van COVID19 patienten met CVD

**Methods**  
DNA van COVID19 patienten met CVD

**Related Request Number**  
-

**Principal Investigator**  
erik van Iperen  
erikvanpeer@gmail.com  
f  
f

## Delivery

| Type                                                                                  | Status                                                                                        | Notes on delivery  |
|---------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|--------------------|
|  Data |  Preparation | No notes available |

[Release data](#)

Your request is currently in the process of delivery. You will be notified when action is required on your behalf.  
In case irregularities have been found with the delivery, please contact the organisation coordinator.

Please mark all deliveries as Received or Cancelled above prior to finalizing a request.

[Finalize request](#)

# Delivery and finalize request

 Release data for request 2002 

**Reference**

 Cancel  Submit

 Finalize request 2002 

Completing this step will result in the closing of the request

The outcome of the request depends on whether all the requested materials have been received by the researcher.

All requested types have been released or received, therefore the request will be marked as 'Delivered'.

 Cancel  Submit

# Approved request

Requestor:

- Sign DTA

CAPACITY datamanager:

- Prepare dataset in digital research environment (DRE)
  - DRE workspace per approved request -> data uploaded
  - Researchers involved in this request get access to this specific workspace:
    - Analysis + document sharing in virtual environment
    - Necessary statistical programs can be installed
    - Data doesn't have to leave this virtual environment

# Requester

- Discuss performed analysis with DAC
- Publication send to DAC
- CAPACITY collaboration -> last authorship
- Acknowledgements -> provided by DAC

# Results

- Number of requests: 26
- Approved: 15
- Rejected: 2
- Revision: 4

# Questions?



Top questions (2)



Anonymous

0 

ICRF: hoe gangbaar is zoiets in de cardiologie? Of was dit geen probleem?



Anonymous

0 

Wie voerde de data in of hoe kwamen de data in Capacity?

Join at

**slido.com**

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# The presentation will start soon



## This webinar will be recorded

Recordings can be made available for knowledge dissemination.



## Questions or remarks?

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## Mute your microphone

Please mute your microphone to minimize background noise by clicking on the “mute”-symbol on the top of your screen.



## What can we improve for the future?

We are happy to hear any additional questions or feedback for our next expert meeting. Please contact us by mail: [robin.verjans@lygature.org](mailto:robin.verjans@lygature.org)

# The Netherlands Cancer Registry

BBMRI.nl & Health-RI Expert meeting

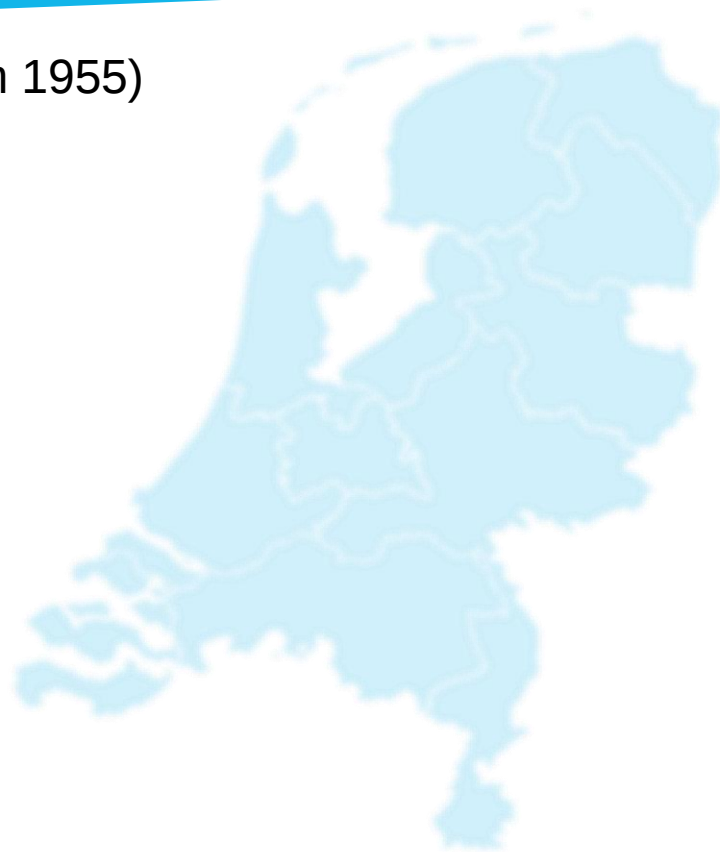
*How to make health(care) data available for research?*

# Table of Contents

- Data collection
  - content
  - legal basis
- Data request
  - procedure
  - lead times
- Challenges & the way forward

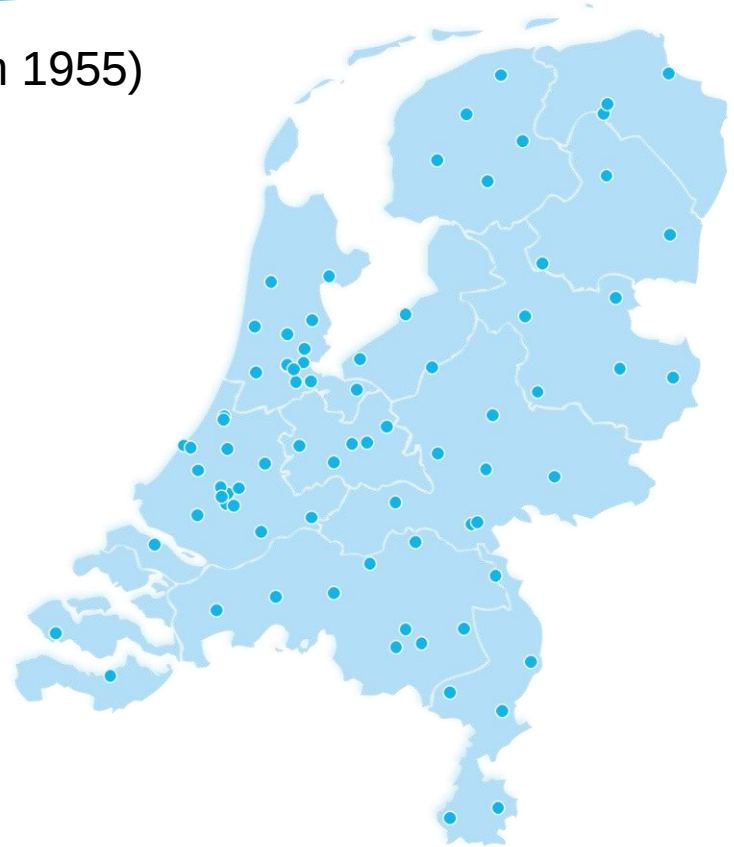
## Netherlands Cancer Registry (1/2)

- National data since 1989 (regional from 1955)

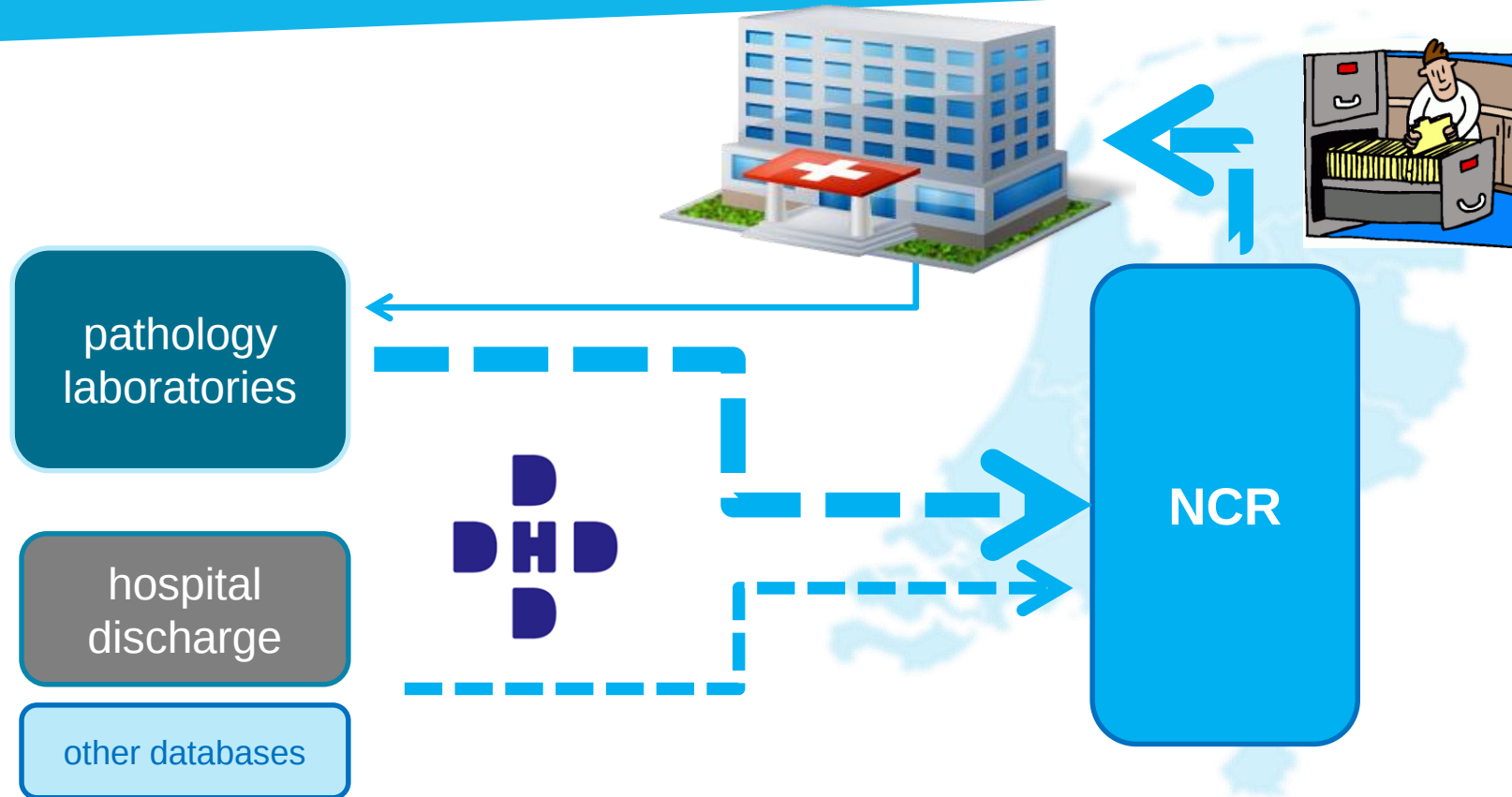


## Netherlands Cancer Registry (2/2)

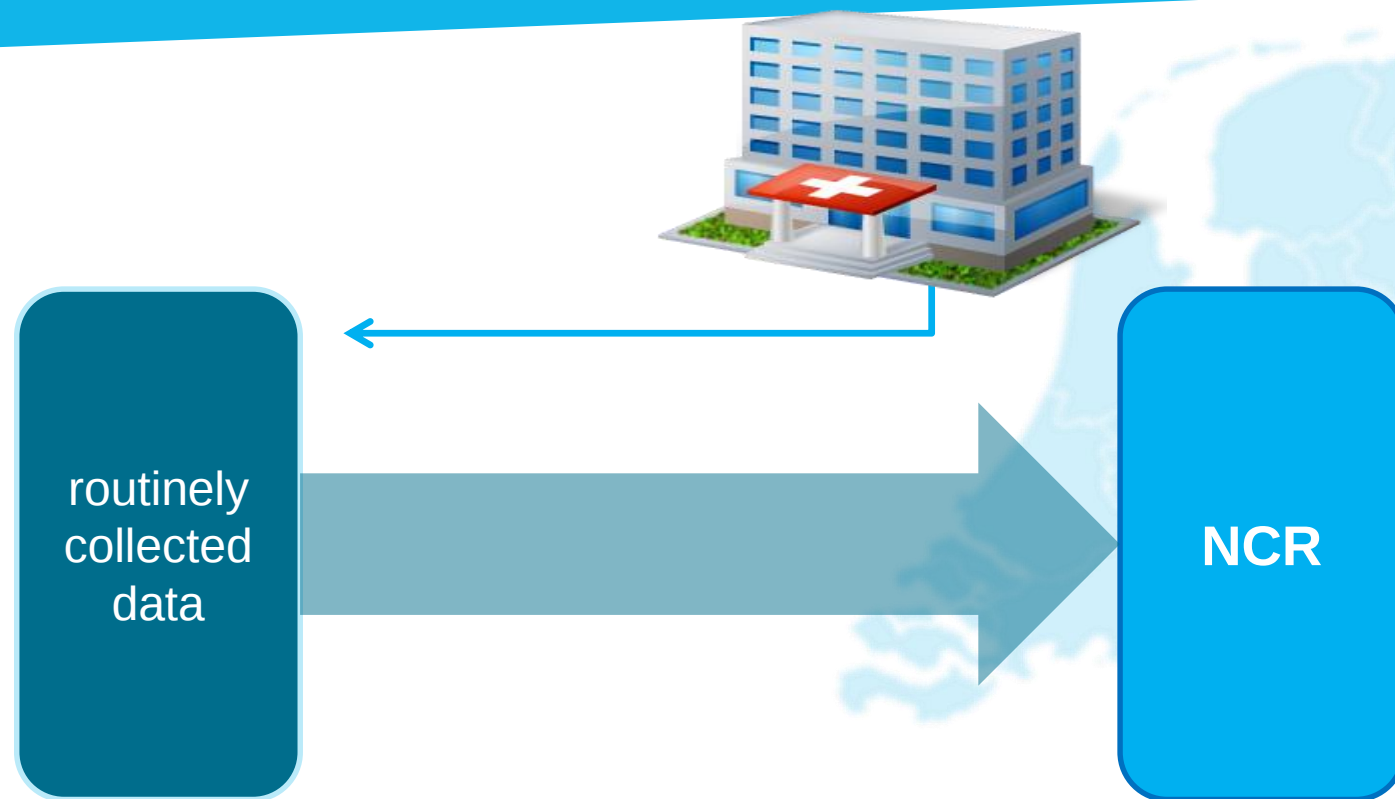
- National data since 1989 (regional from 1955)
- Coverage: 90-95%
- Incidence: >115.000 cases per year
- Database: >2 million cases
- Data managers



## Data collection (1/3)



## Data collection (2/3)

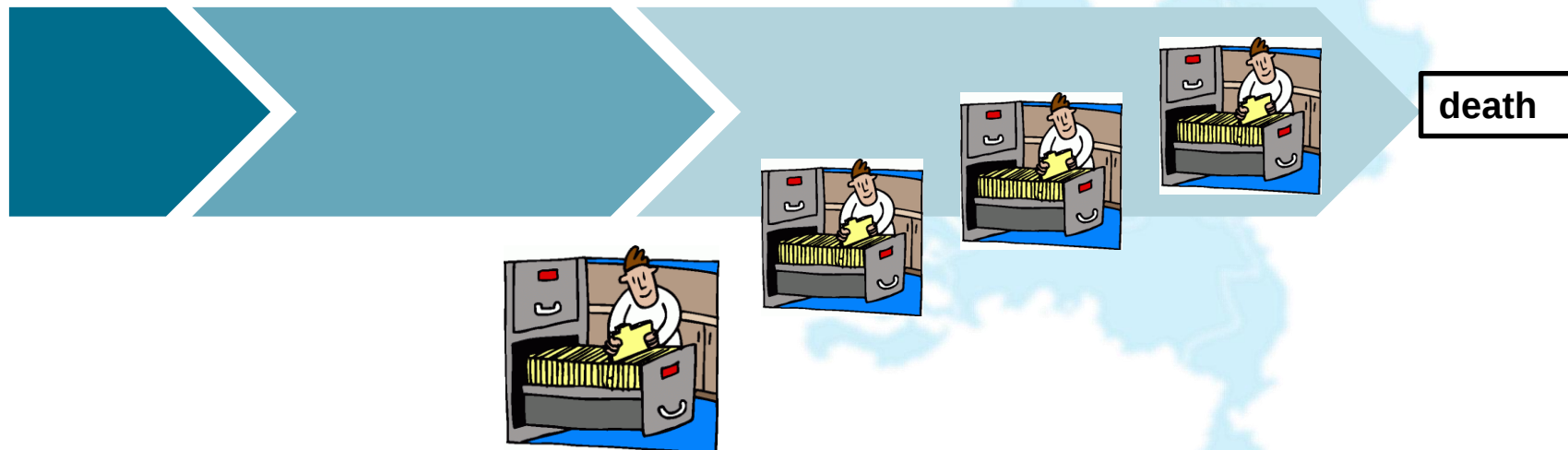


## Data collection (3/3)

diagnosis

primary treatment

follow-up



## Content (1/2)

- Minimal data set (WHO/IARC)
  - demographics (birth date, sex, postal code, vital status)
  - basic tumor characteristics (topography, morphology, stage)
- Additional data
  - diagnosis
  - treatment (type, hospital)
  - follow-up (progression)
- Additional data on tumor types
  - e.g. molecular markers, complications, pathology review





## Coloncarcinoom

Laatste update: januari 2019

| Itemset                                 | 1989-2007                       | 2008-2014        | 2015-heden       |
|-----------------------------------------|---------------------------------|------------------|------------------|
| <b>Patiëntgegevens</b>                  |                                 |                  |                  |
| leeftijd bij diagnose                   | ✓                               | ✓                | ✓                |
| geslacht                                | ✓                               | ✓                | ✓                |
| emigratiedatum                          | ✓                               | ✓                | ✓                |
| overlijdensdatum/laatste contactdatum   | ✓                               | ✓                | ✓                |
| vitale status                           |                                 |                  | ✓                |
| performance status                      |                                 |                  | ✓                |
| ASA classificatie                       |                                 |                  | ✓                |
| co-morbiditeit bij diagnose (standaard) | ✓<br>(vanaf 1993,<br>regionaal) | ✓<br>(regionaal) | ✓<br>(regionaal) |
| <b>Brongegevens</b>                     |                                 |                  |                  |
| instelling van diagnose/behandeling     | ✓                               | ✓                | ✓                |

## Legal basis (1/2)

- Legitimate interest (*gerechtvaardigd belang*)
  - one of the lawful bases for processing personal data
  - a lawful basis is required in order to process personal data in line with the 'lawfulness, fairness and transparency' principle
- Special category data (*bijzondere persoonsgegevens*)
  - statutory exception to the General Data Protection Regulation (GDPR): scientific research and statistical purpose (*wetenschappelijk onderzoek en statistiek*)
- Hospitals
  - contracts / data processing agreements etc.

## Legal basis (2/2)

- Review

- privacy protection (patients / doctors)
- sensitive company information

Supervisory board  
of the NCR

- Members

- jurist
- patient representative
- medical profession
- hospital representative

Data request

## Scientific committees

Supervisory board  
of the NCR

### Data request

| Tumour group       | Scientific committee                                   |
|--------------------|--------------------------------------------------------|
| Breast cancer      | NABON (Nationaal Borstkanker Overleg Nederland)        |
| Hematology         | HOVON (Hemato-Oncologie voor Volwassenen Nederland)    |
| Bone & soft tissue | DSSG (Dutch Sarcoma Study Group)                       |
| Neuro-oncology     | DBTR (Dutch Brain Tumour Registry)                     |
| Endocrine cancers  | DTCCG (Dutch Thyroid Study Group)                      |
| Upper GI           | DUCG (Dutch Upper GI Cancer Group)                     |
|                    | DPCG (Dutch Pancreatic Cancer Group)                   |
|                    | DHCG (Dutch Hepatocellular & Cholangiocarcinoma Group) |
| Lower GI           | PLCRC (Prospectief Landelijk CRC-cohort)               |
| Head & neck        | NWHHT (Nederlandse Werkgroep Hoofd-HalsTumoren)        |
| Urogenital cancers | DUOS (Dutch Uro-Oncology Studygroup)                   |
| Gynaecology        | DGOG (Dutch Gynaecological Oncology Group)             |

## Data request (1/2)

- Website IKNL.nl
  - procedure
  - contact form
- Mail: [gegevensaanvraag@iknl.nl](mailto:gegevensaanvraag@iknl.nl)
- Data request form
  - contract between applicant and IKNL

[Kankersoorten](#)
[NKR](#)
[R & D](#)
[Palliatieve zorg](#)
[Kanker & leven](#)
[NKR cijfers](#)
[COVID-19](#)

[NKR](#) → [Cijfers op maat](#) → [Gegevensaanvraag](#)

Vragen over de NKR

Cijfers op maat

Gegevensaanvraag

Wetenschappelijke toetsing

Koppelingen

Kwaliteitsregistratie

Uitlag NKR cijfers

NKR en klinische studies

PROFEL-studies

Informatiestandaarden

Internationaal

Evaluatie

## Gegevensaanvraag

Het opvragen van gegevens uit de Nederlandse Kankerregistratie (NKR) gebeurt onder strikte privacyvoorwaarden. Elke aanvraag wordt getoetst aan het beleid dat IKNL hanteert voor verstrekking van NKR-gegevens.

### Voor wie?

Bent u arts, onderzoeker, epidemioloog of beleidsmaker bij een ziekenhuis, patiëntvereniging, overheidsinstantie of een wetenschappelijke vereniging of beroepsvereniging, dan kunt u geanonimiseerde gegevens uit de NKR aanvragen voor wetenschappelijk onderzoek of statistiek.

N.B. Patiënten, studenten of andere geïnteresseerden kunnen geen gegevens aanvragen bij IKNL. We verwijzen hen naar [NKR cijfers](#) en [kanker.nl](#).

### Welke gegevens?

In de NKR wordt de incidentie van kanker vastgelegd. De registratie wordt uitgevoerd vanaf diagnose tot en met de afronding van de eerste behandeling. Lees meer over de [geregistreerde gegevens](#) of [bekijk de NKR-items](#) per kankersoort.

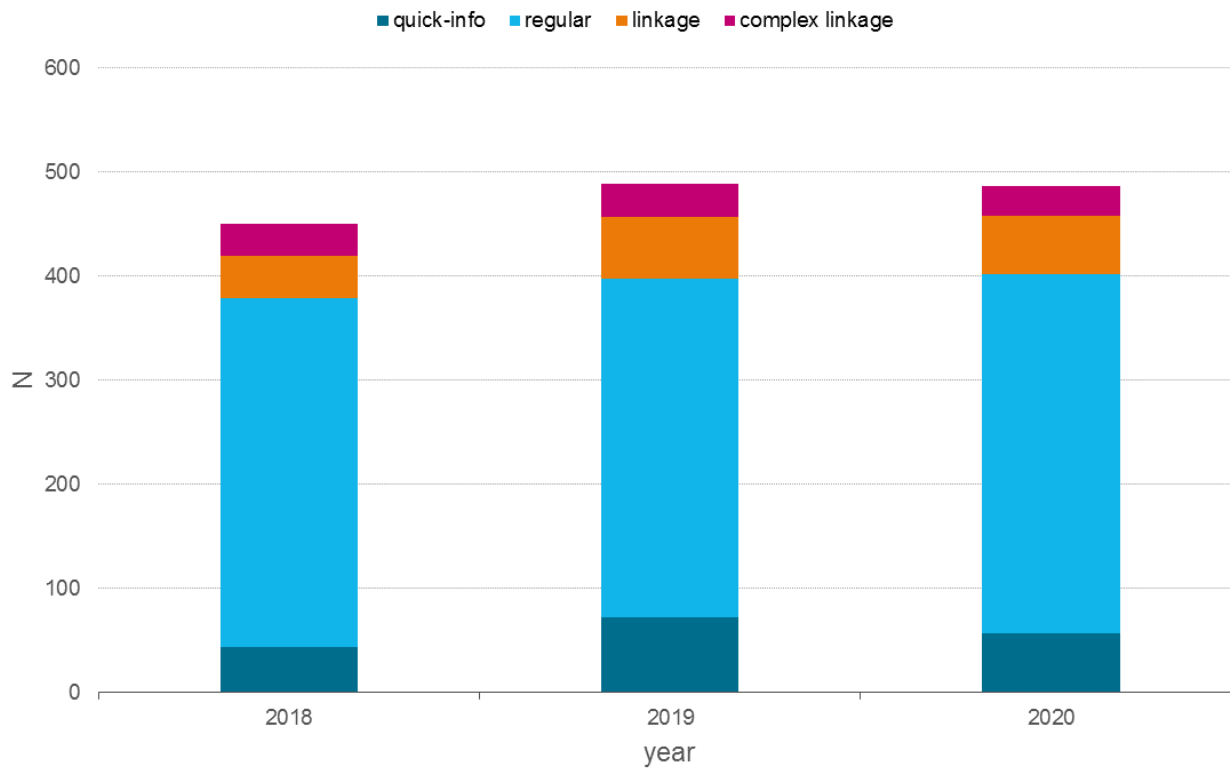
### Onze voorwaarden

IKNL levert alleen gegevens als aan bepaalde voorwaarden wordt voldaan. Het doel van de aanvraag moet overeen komen met de doelstellingen van IKNL: het verbeteren van de oncologische en palliatieve zorg of het ondersteunen van wetenschappelijk onderzoek en statistiek. Gegevens die worden aangevraagd mogen uitsluitend gebruikt worden voor de in de aanvraag genoemde doeleinden. Voor ieder ander (her)gebruik, waaronder aanvullend onderzoek of het ter beschikking stellen aan derden, dient u een nieuwe gegevensaanvraag in te dienen. Als de gevraagde gegevens herleidbaar zijn naar patiënten of behandelaren, gelden aanvullende juridische voorwaarden ten aanzien van de privacywetgeving.

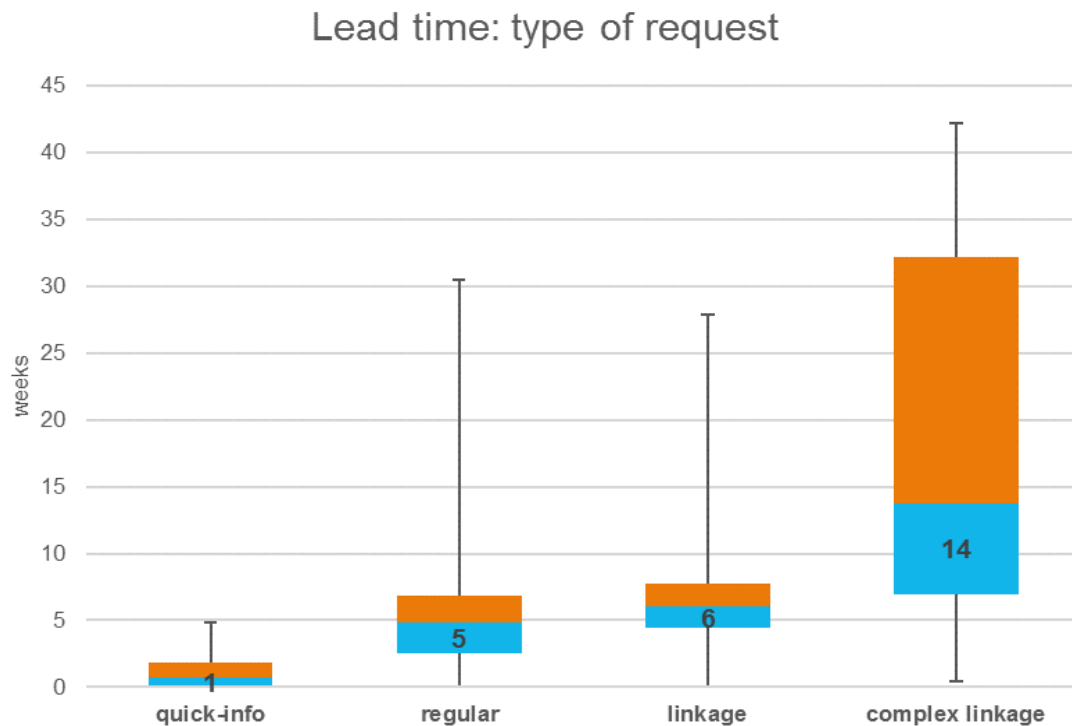
Op de [verstrekking](#) zijn de [Algemene voorwaarden gegevensleveringen](#) van toepassing.

### De procedure

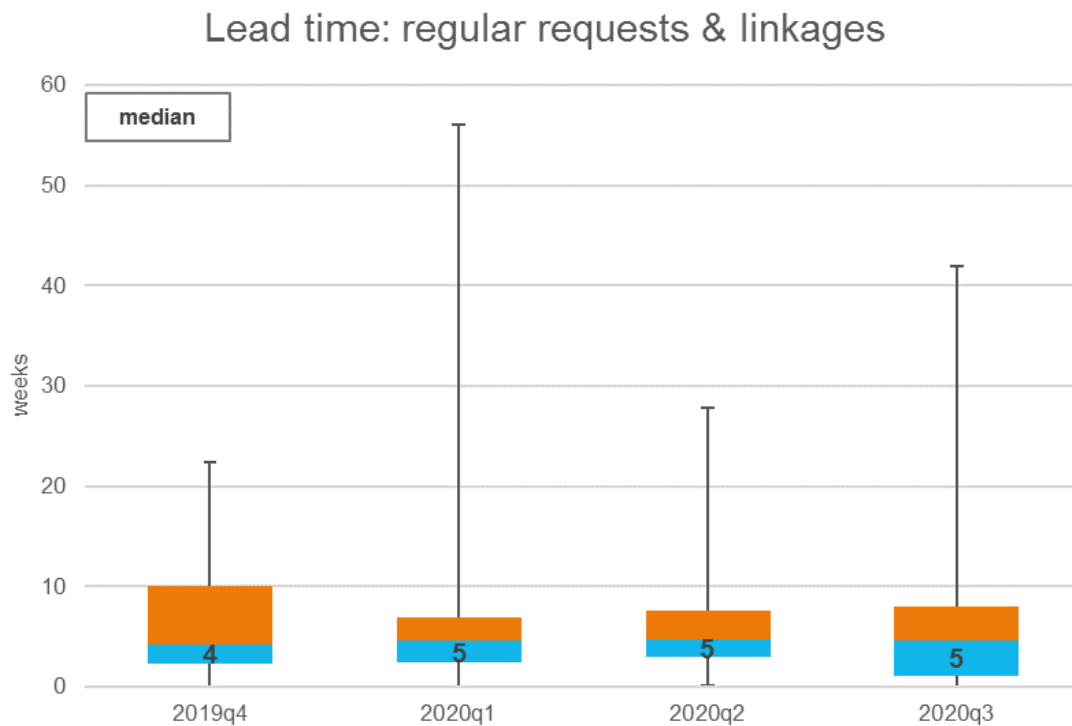
## Data request (2/2)



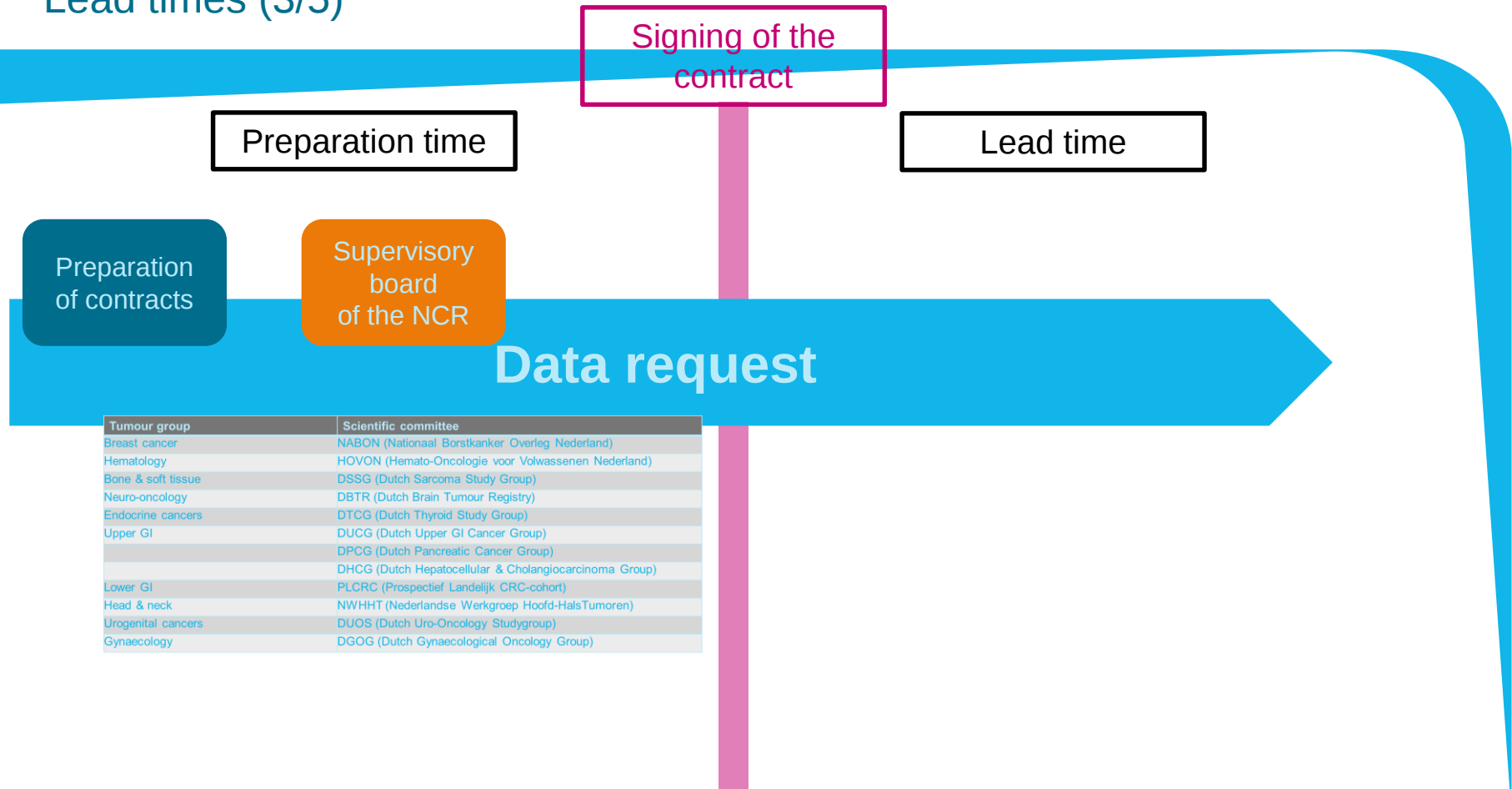
## Lead times (1/5)



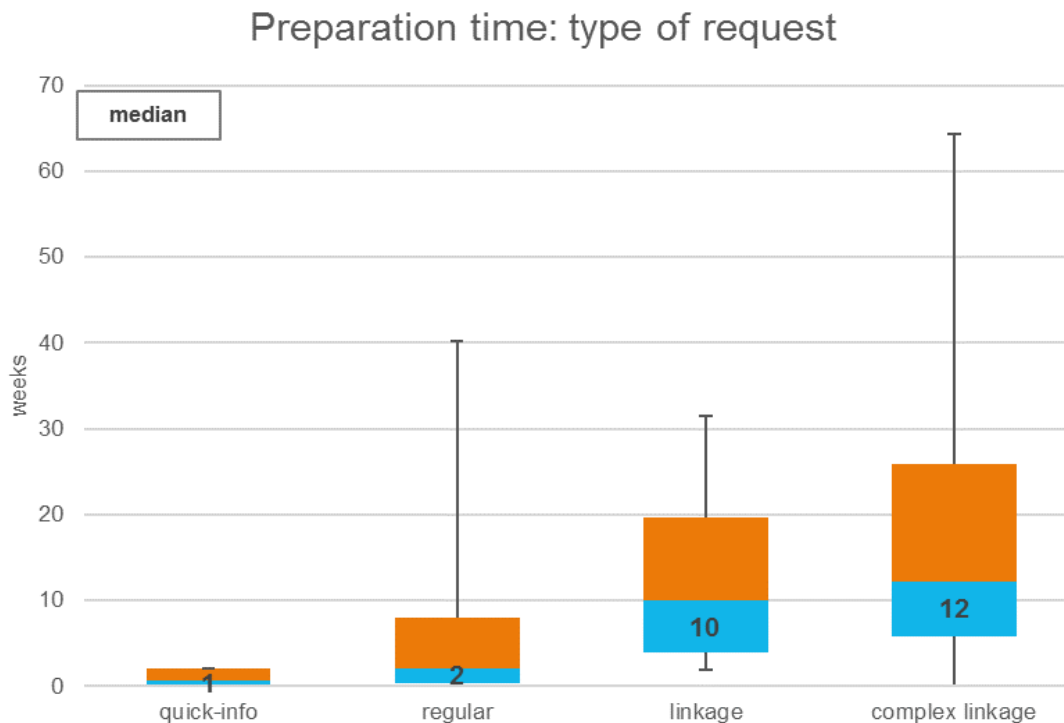
## Lead times (2/5)



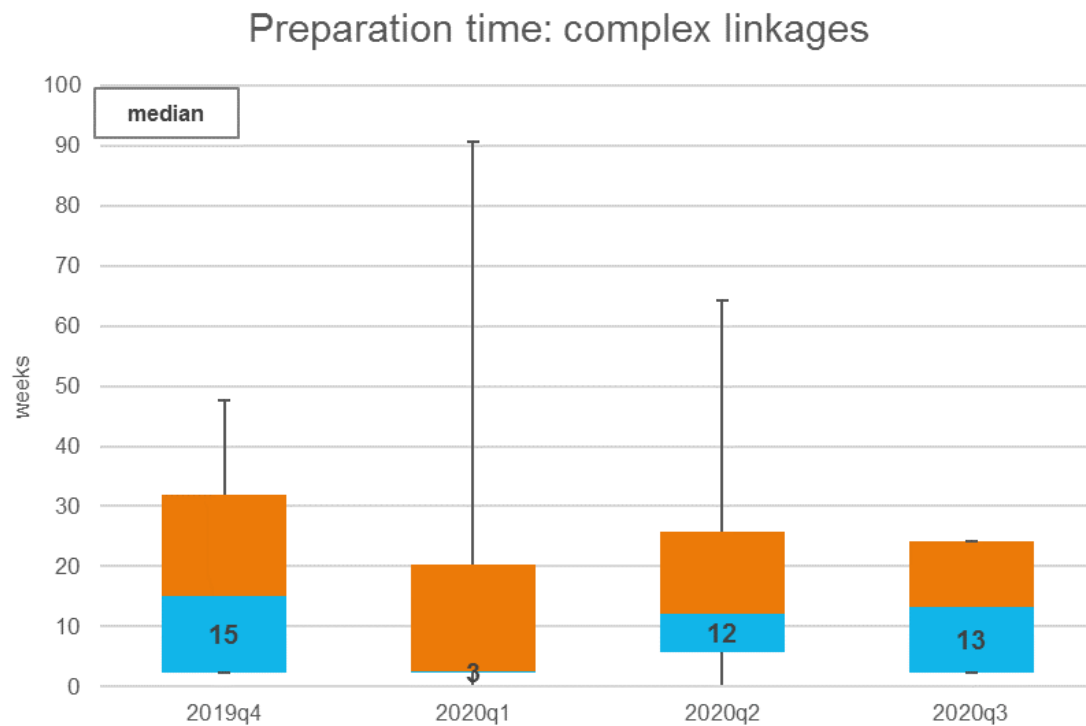
## Lead times (3/5)



## Lead times (4/5)

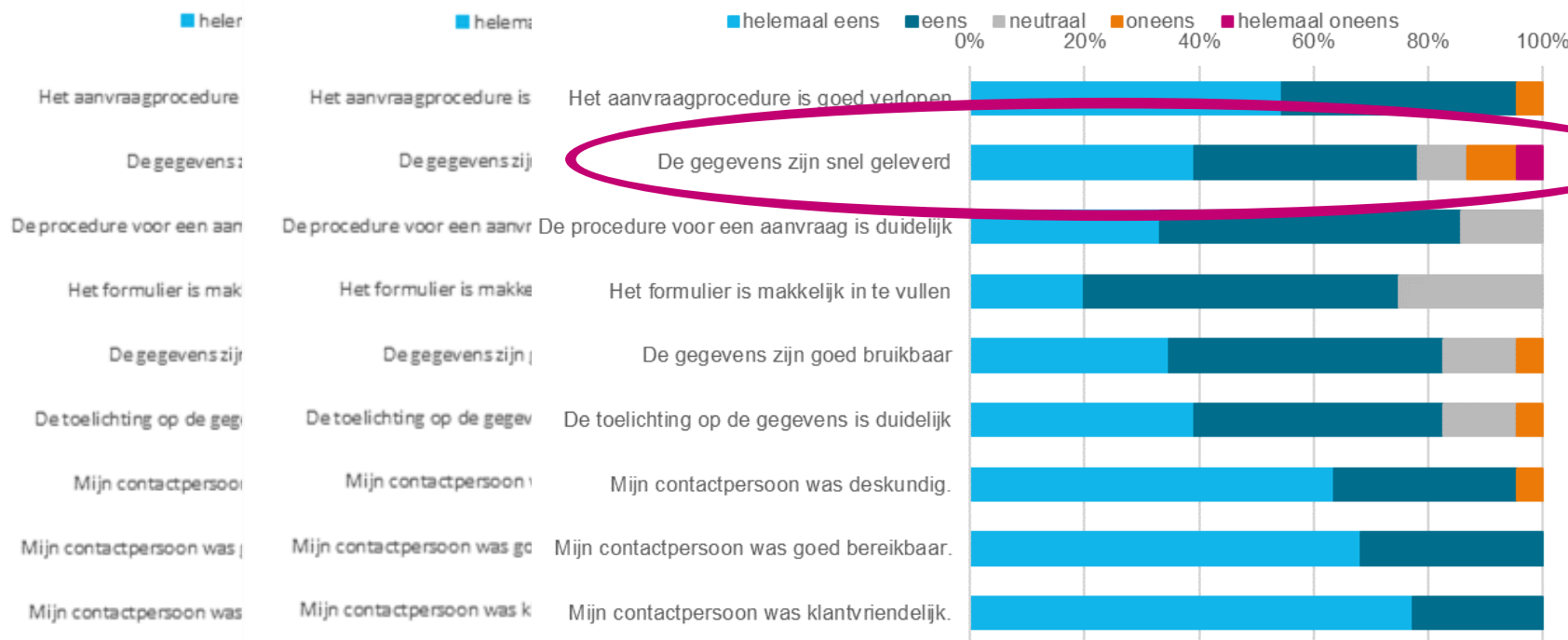


## Lead times (5/5)



# Customer evaluations

## Evaluatie onder aanvragers (n=23)



## Challenges

- Lead times
  - full customization versus standard delivery?
- Transparency of the data request process
- Preparation times
  - legal basis for linkages
- Information on data sets
  - completeness
  - addition / removal of data sets
  - changes over time

The way forward...

# A catalogue for the NCR

- Current situation:
  - Pdf with item set for each tumor type on IKNL website
- Desired situation:
  - Online catalogue with overview of items and details per item (definition, details, values, collection period, quality, etc.)
  - Integration with data request procedure? Complex: “variabelen op maat”, selection criteria
- Planning:
  - Proof of concept (PoC) for one tumor type in Q2 2021
  - Second tumor type in Q4 2021
  - Collection of feedback on PoC for further development

Datum: Oktober 2019  
Auteur: IKNL  
Onderswerp: Itemset mammacarcinoom, Nederlandse Kankerregistratie

**ikNL**  
integraal  
kankercentrum  
Nederland

| ITEMSET                                                           | 1989-2004      | 2005-2010     | 2011-heden     |
|-------------------------------------------------------------------|----------------|---------------|----------------|
| <b>Patientgegevens</b>                                            | 1989-2004      | 2005-2010     | 2011-heden     |
| Leeftijd bij diagnose                                             | ✓              | ✓             | ✓              |
| Geslacht                                                          | ✓              | ✓             | ✓              |
| Land van geboorte                                                 | ✓              | ✓             | ✓              |
| Postcode                                                          | ✓              | ✓             | ✓              |
| Performance status                                                |                |               |                |
| Co-morbiditeit bij diagnose                                       | ✓ (regionaal)  | ✓ (regionaal) | ✓ (regionaal)  |
| Eerdere maligniteit                                               | ✓              | ✓             | ✓              |
| Menopausale status                                                |                |               | ✓              |
| Zwangerschap ten tijde van diagnose                               |                |               | ✓ (vanaf 2018) |
| <b>Diagnosegegevens</b>                                           | 1989-2004      | 2005-2010     | 2011-heden     |
| Instelling van diagnose                                           | ✓              | ✓             | ✓              |
| Instelling van behandeling                                        |                | ✓             | ✓              |
| Patiëntnummer                                                     | ✓              | ✓             | ✓              |
| Specialisme                                                       | ✓ (vanaf 2003) |               | ✓              |
| <b>Tumorgegevens</b>                                              | 1989-2004      | 2005-2010     | 2011-heden     |
| Datum van diagnose                                                | ✓              | ✓             | ✓              |
| Basis voor diagnose                                               | ✓              | ✓             | ✓              |
| Lateralisatie                                                     | ✓              | ✓             | ✓              |
| (Sub)lokalisatie                                                  | ✓              | ✓             | ✓              |
| Morfologie                                                        | ✓              | ✓             | ✓              |
| Tumorgedrag                                                       | ✓              | ✓             | ✓              |
| Differentiatiegraad                                               | ✓              | ✓             | ✓              |
| Multifocaliteit                                                   |                | ✓             | ✓              |
| TNM stadium (klinisch en pathologisch)                            | ✓              | ✓             | ✓              |
| Lymfeklieren onderzoek/positief                                   | ✓              | ✓             | ✓              |
| (Sub)lokalisatie metastasen bij diagnose                          | ✓              | ✓             | ✓              |
| Oestrogenreceptor*                                                |                | ✓             | ✓              |
| Progesteronreceptor*                                              |                | ✓             | ✓              |
| Her2-neu                                                          |                | ✓             | ✓              |
| Her2-neu techniek                                                 |                | ✓             | ✓              |
| Tumorgrootte                                                      |                | ✓             | ✓              |
| DCIS component                                                    |                |               | ✓              |
| <b>Diagnostische gegevens</b>                                     | 1989-2004      | 2005-2010     | 2011-heden     |
| Reden voor diagnostiek                                            |                |               | ✓              |
| DNA onderzoek verricht                                            |                |               | ✓ (vanaf 2014) |
| Palpabiliteit                                                     |                |               | ✓              |
| BIRADS classificatie                                              |                |               | ✓              |
| Moleculaire diagnostiek (mammaprint, oncotype dx)                 |                |               | ✓              |
| Echogeleide punctie/biopsie in dikst (subtag, instelling)         |                |               | ✓ (vanaf 2014) |
| MDO (pre- en post behandeling + datum)                            |                |               | ✓              |
| 1e consult ziekenhuis (datum)                                     |                |               | ✓              |
| 1e consult radiotherapeut bij neoadjuvant (datum)                 |                |               | ✓              |
| 1e consult plastisch chirurg bij amputatie (datum)                |                |               | ✓              |
| 1e consult specialist in tweede ziekenhuis bij verwijzing (datum) |                |               | ✓              |

# A catalogue for the NCR: PoC

Based on Norwegian Cancer Registry catalogue ELVIS (<https://metadata.kreftregisteret.no/>)

The screenshot shows the ELVIS Variables catalogue interface. The top navigation bar includes 'Variables', 'My variables', 'Application form', and 'Help'. A language dropdown menu is set to 'English' (UK flag). The main section is titled 'Variables' and contains a search bar, filters for 'Valid from' and 'Valid to', and a 'Search' button. A sidebar on the left lists 'Cancer sites' with a search bar and a list of categories, including 'Breast' and 'C50 Breast'. The main content area displays a table of variables with columns: Name, Deliverable, Valid from, Tech Name, and an 'All' button. The table lists variables such as 'Additional information in pathology report', 'Age at diagnosis', 'Basis of diagnosis', 'Basis of diagnosis in international standard', and 'Behavior'. Each variable row has a 'more details' icon (three dots) and an 'add to shopping basket' icon (shopping bag). Annotations with red boxes and dotted lines point to various elements: 'shopping basket' points to the shopping bag icon; 'data request' points to the 'Variables' tab; 'variable selection by tumor type' points to the 'Breast' and 'C50 Breast' checkboxes; 'variable (+ details)' points to the 'Age at diagnosis' variable; 'in Norwegian and English' points to the language dropdown; 'more details' points to the three-dot icon; and 'add to shopping basket' points to the shopping bag icon.

| Name                                                                                                              | Deliverable  | Valid from | Tech Name          | All                    |
|-------------------------------------------------------------------------------------------------------------------|--------------|------------|--------------------|------------------------|
| <b>Additional information in pathology report</b>                                                                 | If need be i | 01-01-1953 | tilleggsremisse    | more details           |
| In use when pathology reports have additional information from the original report.                               |              |            |                    |                        |
| <b>Age at diagnosis</b>                                                                                           | Yes          | 01-01-1953 | alderDiagnose      | add to shopping basket |
| Age of the patient at time of diagnosis.                                                                          |              |            |                    |                        |
| <b>Basis of diagnosis</b>                                                                                         | Yes          | 01-01-1953 | basis              | more details           |
| The most reliable method used to confirm the diagnosis for the cancer case.                                       |              |            |                    |                        |
| <b>Basis of diagnosis in international standard</b>                                                               | Yes          | 01-01-1953 | basisInternasjonal | more details           |
| Basis of diagnosis according to international standard from IARC/ENCR/JRC.                                        |              |            |                    |                        |
| <b>Behavior</b>                                                                                                   | Yes          | 01-01-1953 | tumoratferd        | more details           |
| Indicates whether a tumor is malignant, benign or in situ. The fifth digit of morphology code is a behavior code. |              |            |                    |                        |

# Questions?





[www.iknl.nl](http://www.iknl.nl)



[www.linkedin.com/company/iknl](http://www.linkedin.com/company/iknl)



[twitter.com/iknl](https://twitter.com/iknl)



Top questions (1)



Anonymous

0 👍

Bij NHR en Capacity studie is de data invoer (variabelen, definities) gestandaardiseerd aan de hand van het NHR handboek en codeboek. Hoe werkt dit bij IKNL?

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### What is your key takeaway from this expert meeting?

009

Mooie voorbeelden van hoe het in de praktijk gaat

Professioneel en zorgvuldig. Doorlooptijd is wel een issue

Interessant te horen hoe anderen met data aanvragen omgaan!

Capacity toont aan: t kan snel

Meer Samenwerking

(koppelen van) catalogus data zou een mooie stap in de richting van F (FAIR) zijn.

# WE HOPE TO SEE YOU NEXT EXPERT MEETING!

## Program Expert Meeting Series:

|   |                                                   |                                                                                              |
|---|---------------------------------------------------|----------------------------------------------------------------------------------------------|
| 1 | Thursday October 29 <sup>th</sup><br>14.00-15.00  | CBS - Fatima El Messlaki & Ivo Gorissen<br>NHR - Saskia Houterman                            |
| 2 | Thursday November 12 <sup>th</sup><br>14.00-15.00 | Durrer Center - Erik van Iperen & Wanda Hermans-Van Ast<br>IKNL - Peter Prinsen & Vincent Ho |
| 3 | Thursday November 26 <sup>th</sup><br>14.00-15.00 | LifeLines - Trynke de Jong<br>DataHub – Pascal Suppers                                       |