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IMAGINE-study

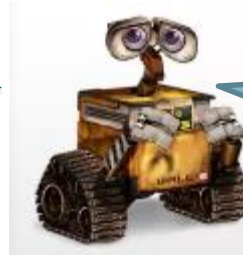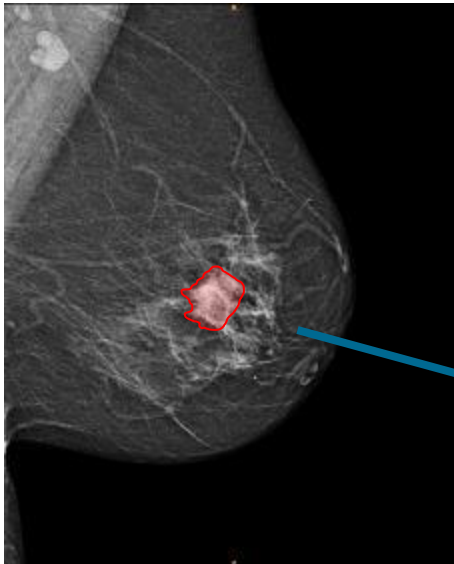**Goal:** **Predicting tumour aggressiveness based on screening mammograms using Artificial Intelligence algorithms**

Why: **Less <u>overdiagnosis</u> of indolent breast cancer**

Less <u>underdiagnosis</u> of aggressive breast cancer

Eventually: optimize recall decisions in screening
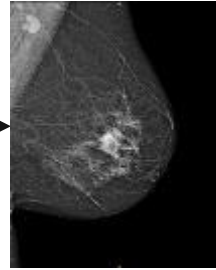
IMAGINE-study

How:
- **Identify image features on screening mammograms of breast cancer patients using AI**

- **Use prediction models to predict cancer aggressiveness with those features**
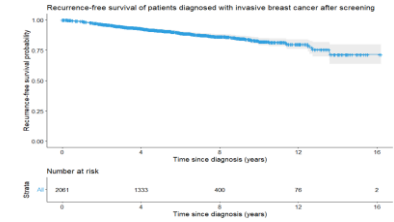
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IMAGINE-study

79,810 screening attendees (2003-2019)

2,115 invasive breast cancers
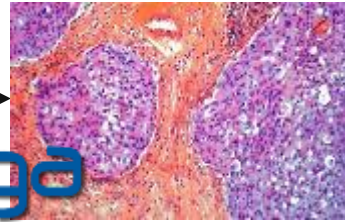
1,455 screen-detected

660 interval cancers
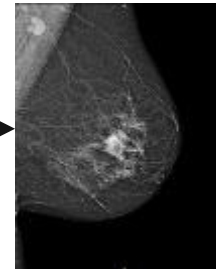
Lesson 1. Process of setting up contracts

Before receiving grant:

- **Negotiations with Screening Organisation (SO)**

- **Contact with Netherlands Comprehensive Cancer Orgnisation**

  (Netherlands Cancer Registry – NCR)

- **Contact with National Archive Pathology (PALGA)**

- **Contact Medlaw Consult for DPIA**

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Lesson 1. Process of setting up contracts

Immediately after receiving grant:

- **Continue negotiations with SO**

- **Consortium agreement between 4 research institutions**

- **Medlaw Consult carried out DPIA**

- **Ethics review by Radboudumc**

Lesson 1. Process of setting up contracts

- **(Legal) persons involved in contracts**

    - **safeguard their organisation, not facilitate research**

    - **may not understand research**

    - **may not understand data flows**

- **Intended routes of data collection may not be feasible / obsolete**

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Lesson 1. Process of setting up contracts

Timeline contracts IMAGINE

- **Contract SO** (screening mammograms)
- **Contract NCR**
- **DTA Consortium**
- **DTA SO for missing screening mammograms**

- Consortium agreement
- **Contract Radboudumc-NCR-PALGA**
- **Contracts 3 hospitals** (diagnostic mammograms)
- **Contracts pathology labs**

Start as early as possible!

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Lesson 2. Explain absence of explicit consent
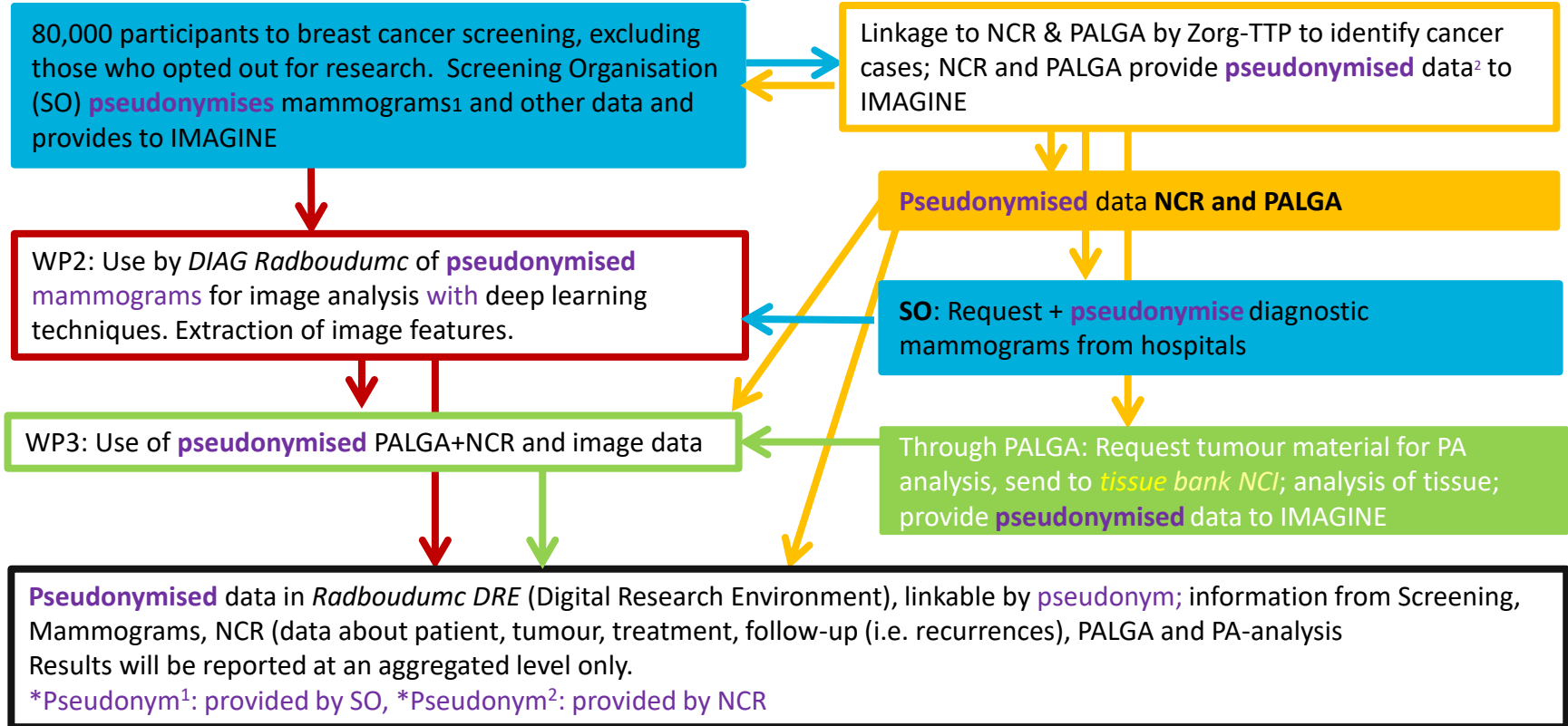
- **No written informed consent from screening attendees for research but opt-out**

- **Legal persons may request written consent from all participants / patients**

- **Therefore Medlaw Consult carried out DPIA**

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Lesson 3. Visualise steps of data collection

79,810 screening attendees (2003-2019)

2,115 invasive breast cancers

1,455 screen-detected

660 interval cancers

Lesson 3. Visualise steps of data collection

80,000 participants to breast cancer screening, excluding those who opted out for research. Screening Organisation (SO) **pseudonymises** mammograms[1] and other data and provides to IMAGINE

Linkage to NCR & PALGA by Zorg-TTP to identify cancer cases; NCR and PALGA provide **pseudonymised** data[2] to IMAGINE

Pseudonymised data **NCR and PALGA**

WP2: Use by *DIAG Radboudumc* of **pseudonymised** mammograms for image analysis with deep learning techniques. Extraction of image features.

SO: Request + **pseudonymise** diagnostic mammograms from hospitals

WP3: Use of **pseudonymised** PALGA+NCR and image data

Through PALGA: Request tumour material for PA analysis, send to *tissue bank NCI*; analysis of tissue; provide **pseudonymised** data to IMAGINE

Pseudonymised data in *Radboudumc DRE* (Digital Research Environment), linkable by pseudonym; information from Screening, Mammograms, NCR (data about patient, tumour, treatment, follow-up (i.e. recurrences), PALGA and PA-analysis
Results will be reported at an aggregated level only.
*Pseudonym[1]: provided by SO, *Pseudonym[2]: provided by NCR

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Lesson 4. Conditions for data exchange/storage

- **GDPR**

- **Pseudonymisation by owner of data or Trusted Third Party**

- **In practice: pseudonymisation of mammograms by project members on secondment to SO and hospitals**
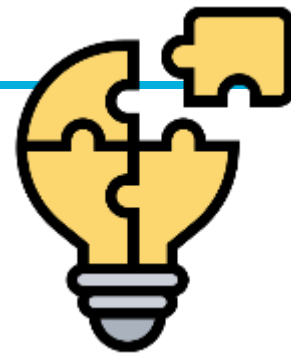
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Lesson 4. Conditions for data exchange/storage

- **Transfer of mammograms complex because size of files and need for secured methods**

- **Secured data drives carried in person from organisations to research institute**

- **Storage of mammograms in secured platform used for analyses (DRE) not**

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Summary

Lessons learned

(1) Start the process of setting up contracts early, even if you have a DPIA

(2) Provide rationale for research with screening data if explicit consent absent

(3) Visualise steps of data collection in study protocol / data management plan

(4) Check expertise & facilities for data pseudonymisation, exchange/storage

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And further……..

- **Hope no catastrophy like COVID pandemic complicates the study …..**