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Streamline executing your research



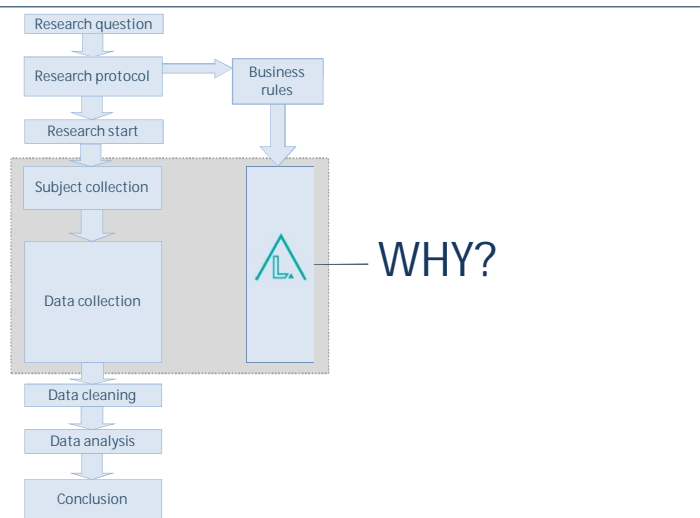
Ldot: Why and how Ldot assists you

MEMIC - Maastricht University

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Ldot positioning



```
graph TD; RQ[Research question] --> RP[Research protocol]; RP --> RS[Research start]; RP --> BR[Business rules]; BR --> SC[Subject collection]; SC --> DC[Data collection]; DC --> DCL[Data cleaning]; DCL --> DA[Data analysis]; DA --> C[Conclusion];
```


WHY?

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 Why (1)?

- Simplify execution
 - Don't loose track: Ldot is especially helpful in studies with a high number of participants and/or complex protocols

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 Why (2)?

- Immediate insight in study status
 - Pro-active: only get alerted for actions that require attention
 - Visualise study subject progress (e.g. charts)

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 Why (3)?


- Protocol execution standardisation:
 - **Objective**
Avoid subjective interpretations of your protocol amongst multiple users (in multiple centres)
 - **Centralised knowledge**
Avoid being dependent of knowledge of certain individuals
 - **Easy to learn and execute**

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 Why (4)?

- Minimisation of required team efforts
 - **Automatic execution of protocol rules**
 - **Automatic execution of specific actions**
 - **Automatic registration by third party applications**

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Why (5)?

- Central, safe storage of logistical data
 - Avoid fragmented data storage
 - Avoid data loss
 - Avoid data leaks

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Ldot: Who, what and when?

```

    graph TD
      A[Research question] --> B[Research protocol]
      B --> C[Research start]
      B --> D[Business rules]
      C --> E[Subject collection]
      E --> F[Data collection]
      F --> G[Data cleaning]
      G --> H[Data analysis]
      H --> I[Conclusion]
      D --> E
      D --> F
  
```

The flowchart illustrates the research process. It starts with a 'Research question' leading to a 'Research protocol', which then leads to 'Research start'. From 'Research protocol', an arrow points to 'Business rules'. 'Research start' leads to 'Subject collection', which then leads to 'Data collection'. 'Business rules' has arrows pointing to both 'Subject collection' and 'Data collection'. 'Data collection' leads to 'Data cleaning', which leads to 'Data analysis', and finally to 'Conclusion'. A vertical box highlights the 'Subject collection' and 'Data collection' steps, with a callout box containing the Ldot logo and the questions 'Who?', 'What?', and 'When?' pointing to it.

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Who?

Entities are fully customisable per study

- Name them as you'd like, as many as you need
- Define entity hierarchy
- Define entity details:
 - Detail sections
 - Variables within selected sections

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What (1)?

<u>Event</u>	<u>Event action</u>
	Initiating action, e.g. enrolled
Send Informed Consent	To-do: send Sent Will not be sent
Receive Informed Consent	To-do: Receive signed IC form Received Will not be received
	Next to-do action(s)

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 What (2)?

- Flow is/can be specific for:
 - Entity
 - Centre
 - Study group

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 What (3)?

- General
- Phone
- Email/SMS
- Export
- Randomisation
- Waiting

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 When?


- To do actions are shown on several levels
 - Home screen
 - To do lists
 - Sorted per type and action
 - Individual level
 - Calendar view
- Registered actions are shown on individual level

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 Other functionality Ldot (1)

- Loss to follow-up
 - Three levels
 - PreLOF (before inclusion)
 - Exclusion
 - LOF (after inclusion)

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Other functionality Ldot (2)

- Overviews
 - Default types
 - Pie
 - Bar
 - Line
 - Table
 - Tailor-made types, like a response overview
- Barcode scanner

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Integration with third party tooling

```


graph TD
    RQ[Research question] --> RP[Research protocol]
    RP --> RS[Research start]
    RS --> SC[Subject collection]
    SC --> DCS["(3rd party) data collection software"]
    SC --> DC[Data collection]
    DCS --> DC
    DC --> DCL[Data cleaning]
    DCL --> DA[Data analysis]
    DA --> C[Conclusion]
    MRD[(MEMIC Research Database)] --> DCL
    MRD --> DA
    LD[(Ldot Database)] --> DCL
    LD --> DA
  
```

castor ✓
 NIBIA ✓ (test)
 OpenClinica ✓ (test)
 Q1-2017

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 Ldot Manager


- Allows users with granted access to:
 - Export/import subject data
 - Remove subjects
 - Manage study users
 - Manage third party tooling settings

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 Ldot Study Builder

1. To build your own Ldot schedule, first get to know your study schedule: Visualise your study into a flow-chart, e.g. using Microsoft Visio; Consider all possible outcomes of an action. This may take some time!
2. Build your schedule based on your flow-chart

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Security (1)


- Ldot is GCP* compliant and conforms to WBP**
 - All privacy sensitive data are stored separately from research data
 - All changes applied to the database are stored in an *audit*-layer:
 - What
 - Who
 - When

* International quality standard for clinical trials involving human subjects
** Dutch Data Protection Act
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Security (2)

- Secure user management, based on membership roles or user-specific rights
 - Specific parts of the system
 - Study
 - Study centre
 - Study group
 - ...

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 Security (3)

- Secured data transfer over an encrypted HTTPS protocol
- Storage in secure Oracle database environment (NEN-7510) in MUMC+
- Back-up:
 - Daily (can be restored to a specific day in the last week)
 - Hourly (can be restored to the data condition one hour ago)

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 Live demo



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Integration with other applications: Open Clinica (1)

Automatically add subject

```

sequenceDiagram
    participant User
    participant OpenClinica
    participant Ldot
    User->>OpenClinica: add subject
    OpenClinica-->>User: confirmation
    OpenClinica->>Ldot: request subjects
    Note over Ldot: every minute
    Ldot-->>OpenClinica: list of subjects
    Ldot->>Ldot: add unknown subjects
    
```

OpenClinica
Open Source for Clinical Research

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Integration with other applications: Open Clinica (1)

CRF progress detection

```

sequenceDiagram
    participant User
    participant OpenClinica
    participant Ldot
    User->>OpenClinica: fill in crf
    OpenClinica-->>User: confirmation
    OpenClinica->>Ldot: send e-mail
    Ldot->>Ldot: register eventaction
    Ldot->>Ldot: prepare e-mails if necessary
    Ldot-->>User: send email(s) if necessary
    
```

OpenClinica
Open Source for Clinical Research

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Integration with other applications: NBIA

New image status

```

sequenceDiagram
    participant User
    participant NBIA
    participant Ldot

    User->>NBIA: perform qc on series
    NBIA-->>User: qc confirmation
    Note over NBIA: every x minutes
    NBIA->>Ldot: send series data
    Ldot->>NBIA: request extra data
    Ldot-->>NBIA: extra data
    Ldot->>Ldot: register eventaction
    Ldot->>Ldot: prepare e-mails if necessary
    NBIA->>User: send email(s) if necessary
  
```

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Integration with other applications: Castor EDC

- Add subject (Ldot → Castor)
- Initiate new survey (Ldot → Castor)
 - Returns URL for Ldot to send invitations
- Survey completed (Castor → Ldot)
- Q1 2017: eCRF completed (Castor → Ldot)

castor


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 Integration with other applications: Qualtrics (Q1 2017)

- Initiate new survey
- Survey completed (Qualtrics → Ldot)



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