



## Center for data and information management

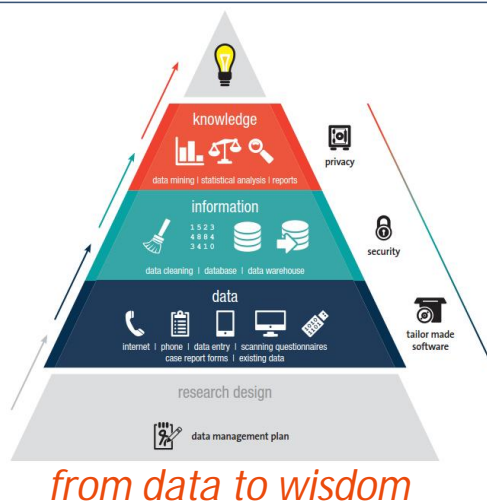
*Guide your study logistics with: Ldot*

### Presentation outline

1. About MEMIC
2. MEMIC web applications: General
3. Ldot



## About MEMIC



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About MEMIC

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## Presentation outline

1. About MEMIC
2. MEMIC web applications: General
3. Ldot

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Presentation Outline

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## Security (1)

- 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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## Security (2)

- All changes applied to the database are stored in an *audit*-layer:
  - What has been changed?
  - Who changed it (user ID, system information)?
  - When was it changed?
- All software is GCP\* compliant and conforms to WBP\*\*
  - All privacy sensitive data are stored separately from research data
- All MEMIC data managers:
  - are GCP certified
  - have signed a vow of secrecy

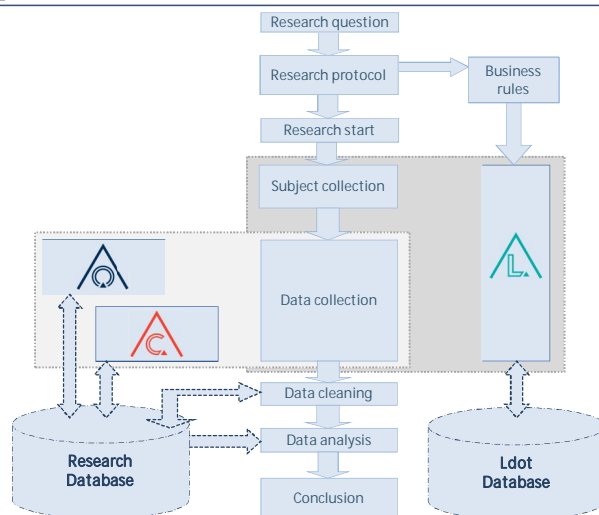
\* International quality standard for clinical trials involving human subjects

\*\* Dutch Data Protection Act

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### MEMIC applications in a research project



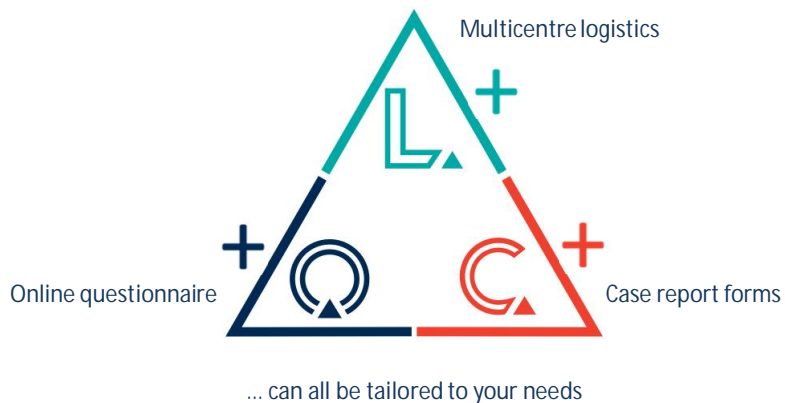
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MEMIC web applications

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### MEMIC Web Applications



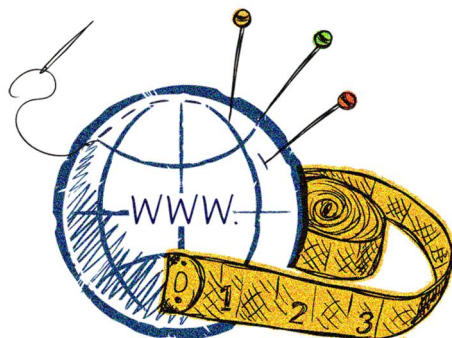
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## MEMIC Web Applications



Fully tailor-made applications

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## Presentation outline

1. About MEMIC
2. MEMIC Web Applications
3. Ldot

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## Who?

Entities are fully customisable per study

- Own naming
- Hierarchy
- Detail sections
  - Personal / Organisational
  - Contact
  - Financial
  - Patient / Caregiver
  - Custom
- Variables within selected sections
  - Visible
  - Editable
  - Optional / Desired / Required

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## What (1)?

Events: every event that a study subject should (or could) go through, in order to successfully complete the study for this subject

Examples:

- Informed consent
- Questionnaire

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## What (2)?

Actions: all actions that can be performed within an event, in the end resulting in successful or unsuccessful completion of the event

Examples (Event Informed Consent):

- To-do date: Send Informed Consent
  - (Sent/ Will not be sent)
- To-do date: IC expected to be returned
  - (Received/Will not be received)

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## When?

Event action triggers:

Business logic of all event actions are stored in "triggers": What should be done after a certain action was registered, and when?

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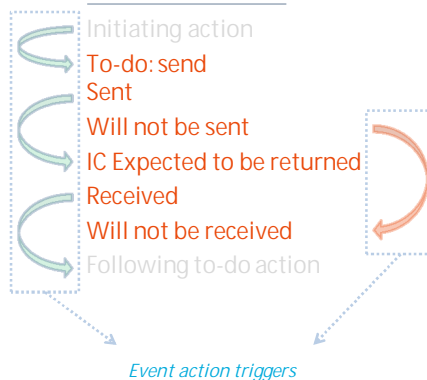


## Events, event actions and triggers: Example

### Event

Informed Consent

### Event action



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## Action types

- General
  - finish/abort
  - (appointment) date
  - specific question
- Phone
- Email/SMS
  - Fully customisable
  - Subject tailored (email only)
  - Attachments (email only)
- Export
  - Excel: all subject variables
  - Possibility to create tailored PDF or RTF-documents
- Randomisation

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## Action types: Randomisation

Ldot selects a random group by multiple randomisations amongst all available groups and selecting the first group that has been randomised three times

Settings:

- Minimum/maximum block size
- Max 5 outcome groups
  - Distribution share
- Unlimited number of stratae
  - Max 5 groups per stratum

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## What should be done?

- To do actions are shown on several levels:
  - Home screen
  - To do list
    - Sorted per type and action
    - Individual level
- Added Q2 2016:
  - Calendar module

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## What has been done?

- Registered actions are shown on individual level:
  - Textual, sorted in event structure.  
Functionality:
    - Add/edit/remove action
    - Add/edit remarks
  - Being developed: timeline module

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## Other functionality (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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## Other functionality Ldot (3)

- Integration with MEMIC applications (Cdot/Qdot/...)
  - Automatically send invitations and reminders
    - For Qdot possible with automatic login link
  - Live presentation of response and CRF completeness (visual and action level)
- Integration with third-party applications
  - Open Clinica
  - BMIA/NBIA
  - Castor EDC
  - ...

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## Ldot specific security

- Secure user management, based on membership roles or user-specific rights
- Can grant or decline access to:
  - Specific parts of the system
  - Study
  - Study centre
  - Study group
  - ...

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## Live demo



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