

# Tablet-PCs for clinical studies

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NovaXon

A tablet PC is shown at an angle, displaying a web-based interface for clinical study data entry. The interface includes a header with a logo and navigation tabs. Below the header, there are sections for 'Demographics', 'Medical Conditions', and 'Measurements'. The 'Measurements' section contains a table with columns for 'Height', 'Weight', and 'Blood Pressure'. The 'Height' column has a value of '1.67 m', and the 'Weight' column has a value of '70 kg'. The 'Blood Pressure' column has a value of '120/80 mmHg'. At the bottom of the screen, there are navigation buttons for 'Login', 'Main', 'Subjects', 'Data Entry', and 'Exports'. A 'Help' button is also visible in the bottom right corner.

NovaXon

# overview

- introduction NovaXon
- brief introduction XClin
- tablet PC's for clinical studies
- real life example

# NovaXon

## development of clinical software

- XClin software for clinical studies
  - different users
    - same data
    - different rights
  - paper forms → e - Case Record Forms (eCRF)
  - tailor made per study
- Electronic Patient Record system



# several users with access to CRF

User: Investigator, Last Connection: 2005-07-18 13:46:50 (From: 81.68.195.185)

**Baseline** Subject: 023-JP

Demography Medical Condition Ulcer Surgery Signature

Height cm

Symptoms Since ?

Race

investigator

monitor

Patient

CRF

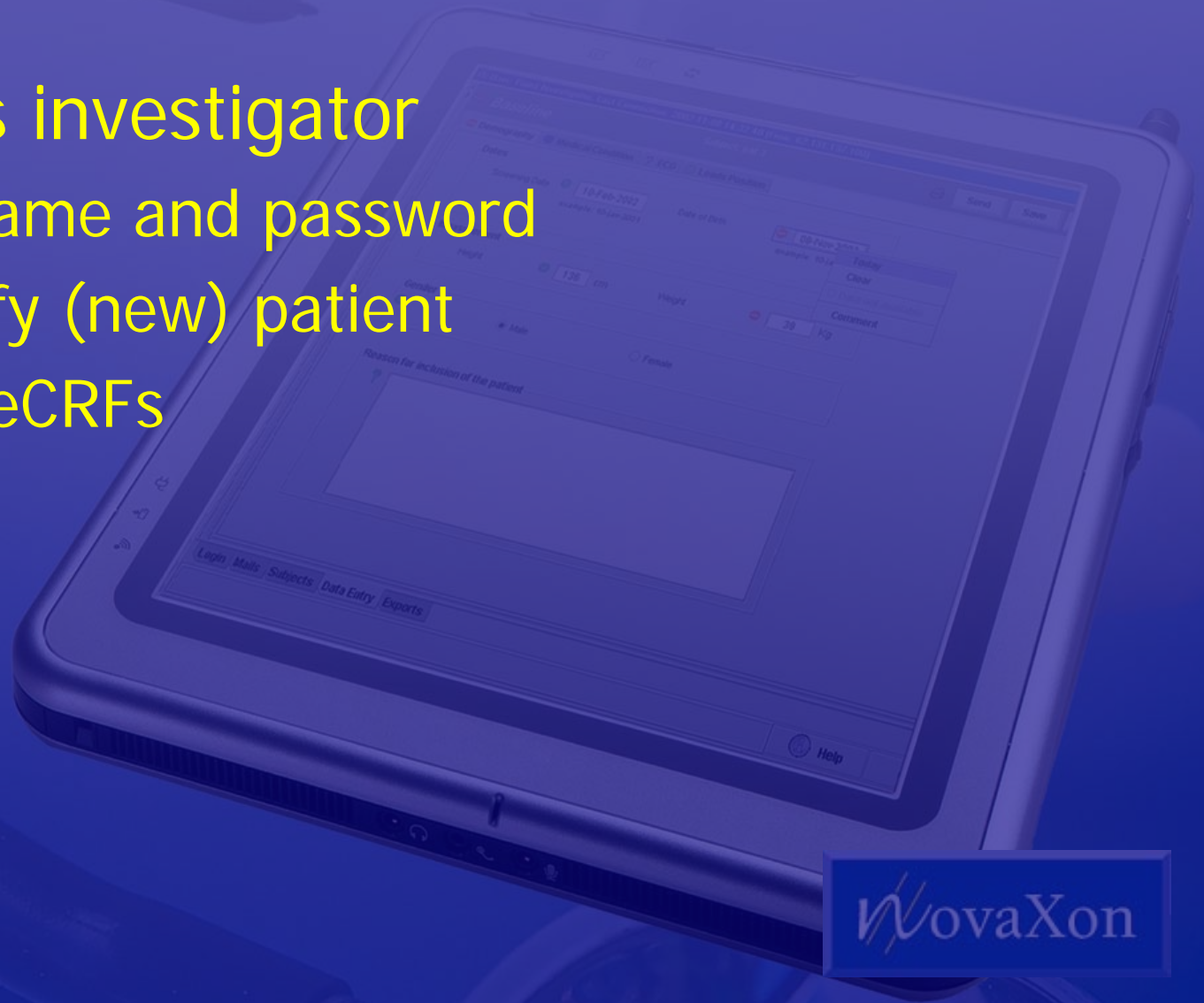
Registrator

police

celebrating

# short example

- ◆ login as investigator
  - username and password
  - identify (new) patient
  - fill in eCRFs





# ? *Baseline*

Subject: 023-JP

- ? Demography
- ? Medical Condition
- ? Ulcer
- ? Surgery
- ? Signature

### Dates

Screening Date ?  Symptoms Since ?   
example: 10-jan-2001 example: 10-jan-1987

### Measurement

Height ?  cm Weight ?  Kg

### Race

?  Asian  Caucasian  Negroid  Other

### Reason for inclusion of the patient


- Login
- Mails
- Subjects
- Data Entry**
- Exports

on line



# ? Baseline

Subject: 023-JP



- ? Demography
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- ? Surgery
- ? Signature

Dates

Screening Date ?  example: 10-jan-20 Symptoms Since ?  example: 10-jan-1987

Today

Clear

Data not available

Comment

Measurement

Height ?  cm      Weight ?  Kg

Race

?  Asian     Caucasian     Negroid     Other ?

Reason for inclusion of the patient

?

- Login
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- Exports

on line





# Baseline

Subject: 023-JP



Send

Save As Draft

Cancel

- Demography
- Medical Condition
- Ulcer
- Surgery
- Signature

## Dates

Screening Date   Symptoms Since

example: 10-jan-2001 example: 10-jan-1987

## Measurement

Height  cm Weight  Kg

## Race

Asian  Caucasian  Negroid  Other

## Reason for inclusion of the patient

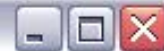
- Login
- Mails
- Subjects
- Data Entry
- Exports

Download Successful

Help

on line





# Baseline

Subject: 023-JP



Send

Save As Draft

Cancel

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### Dates

Screening Date   Symptoms Since    
example: 10-jan-2001 example: 10-jan-1987

### Measurement

Height  cm Weight  Kg

### Race

Asian  Caucasian  Negroid  Other

### Reason for inclusion of the patient

- Login
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Help

on line



# Baseline

Subject: 023-JP



Send

Save As Draft

Cancel

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- Signature

## Dates

Screening Date   Symptoms Since    
example: 10-jan-2001 example: 10-jan-1987

## Measurement

Height  cm Weight   Kg

Number is not between 40.0 and 120.0

## Race

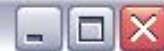
Asian  Caucasian  Negroid  Other

## Reason for inclusion of the patient

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Help

on line



# Baseline

Subject: 023-JP



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- Signature

## Dates

Screening Date   Symptoms Since   
example: 10-jan-2001 example: 10-jan-1987

## Measurement

Height  cm Weight  Kg

- Clear
- Data not available
- Comment

## Race

Asian  Caucasian  Negroid  Other

## Reason for inclusion of the patient

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Help

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# Baseline

Subject: 023-JP



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Help

on line



# login as monitor

- ◆ access to same data
- ◆ no input rights (flexible)
- ◆ monitoring rights





# Baseline

Subject: 023-JP



Send

Cancel

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## Dates

Screening Date



19-Dec-2005

example: 10-jan-2001

Audit

Data reviewed

example: 10-jan-1987

Data source verified

Frozen

Data required

Data not available is fine

Error

Comment

Query

## Measurement

Height



cm

Data required

Data not available is fine

Error

Comment

Query



39

Kg

## Race



Asian

Caucasian

Negroid

Other



## Reason for inclusion of the patient



- Login
- Mails
- Subjects
- Data Entry**
- Exports



Help

on line



# Baseline

Subject: 023-JP



Send

Cancel

- Demography
- Medical Condition
- ? Ulcer
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- ? Signature

## Dates

Screening Date

19-Dec-2005

Symptoms Since ?

?

example: 10-jan-2001

example: 10-jan-1987

## Measurement

Height ?

?

cm

Weight ?

## Race

?

Asian

Caucasian

Negroid

Other

## Reason for inclusion of the patient

- Audit
- Data reviewed
- Data source verified
- Frozen
- Data required
- Data not available is fine
- Error
- Comment
- Query



Help

on line



# Baseline

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# Electronic Data Capture

- ◆ quality of data
  - intelligent forms
- ◆ time saving
- ◆ full audit trail. Who did what when why
- ◆ automated adverse event notification
- ◆ all types of data possible
- ◆ status / progression reports

# mobile computing

## additional advantages

### ◆ access to data, anywhere, anytime

#### ■ data input as close as possible to source

- ◆ patient bedside
- ◆ surgery room

#### ■ data review at convenient time / place

- ◆ hotel room, airport
- ◆ source data verification without internet access

#### ■ online: wireless internet, UMTS

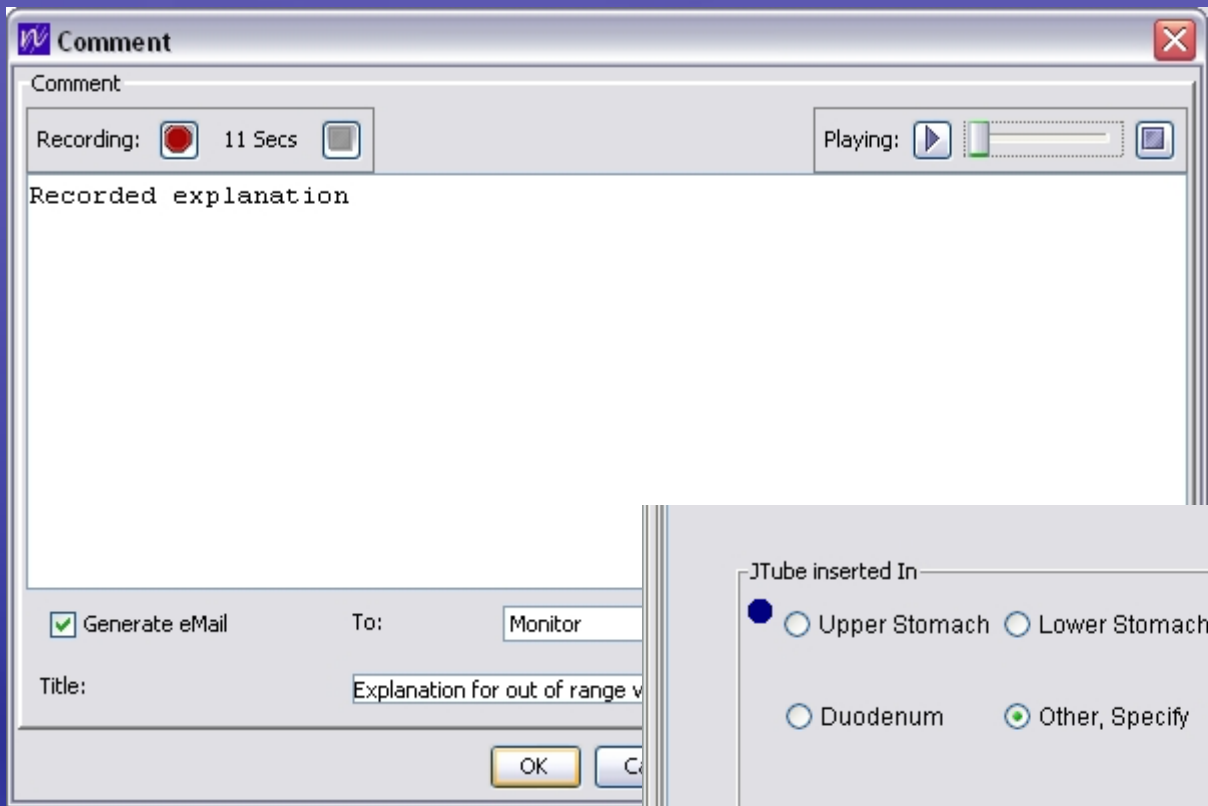
#### ■ offline

} in parallel

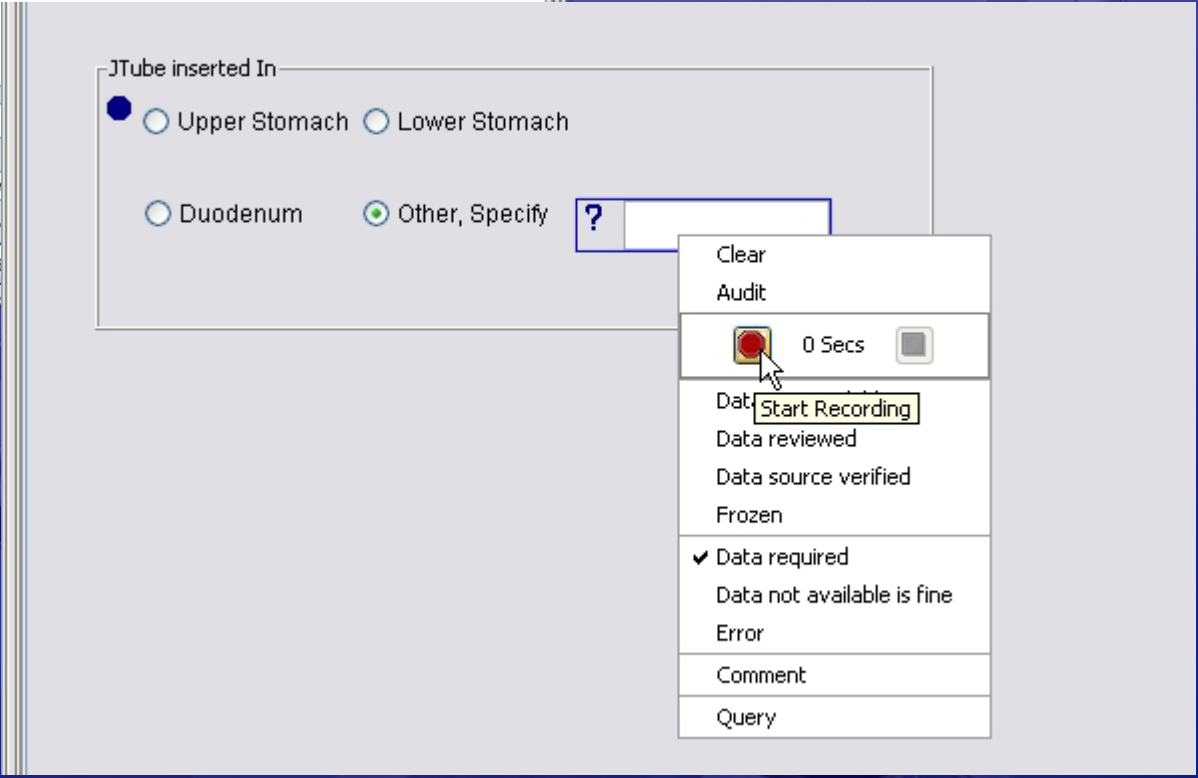
# Tablet PC in clinical studies

ideal for mobile computing

- clipboard look and feel
  - ◆ large screen, small weight
  - ◆ on screen writing
- interaction patient – investigator
- handwriting recognition
- voice recording
- electronic signature



recording as  
comment



recording as part  
of datafield





# Baseline

Subject: 023-JP



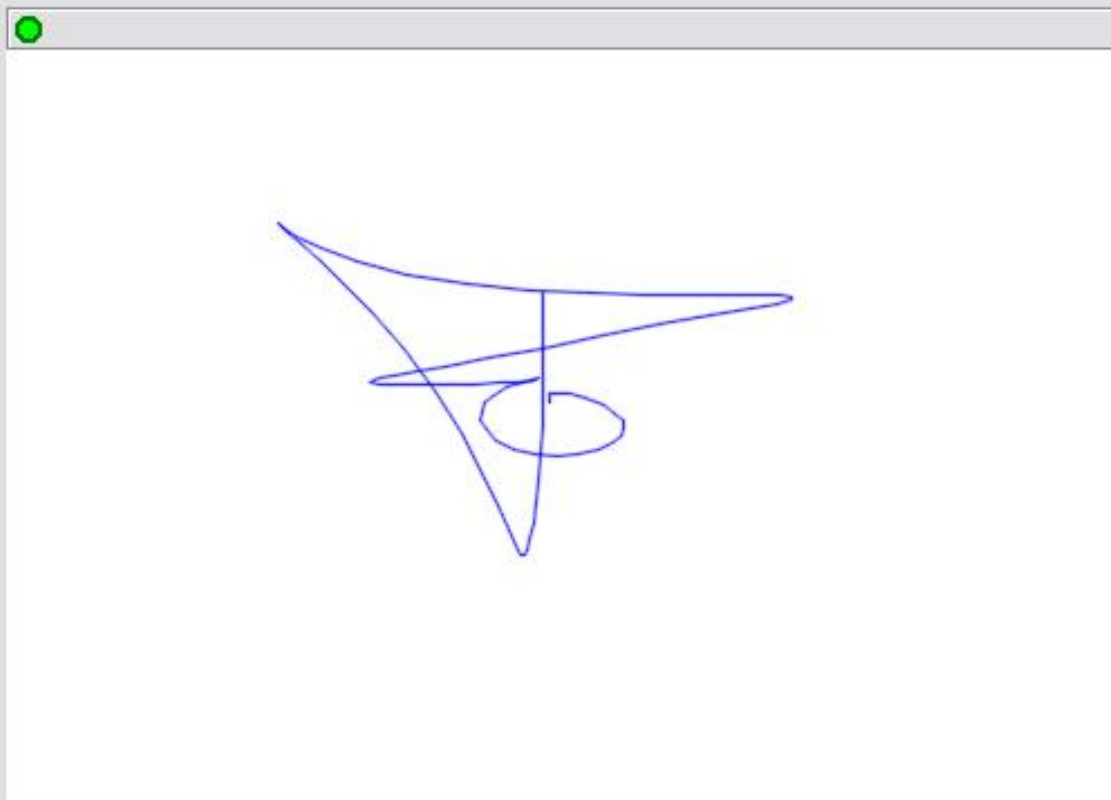
Send

Save As Draft

Cancel

- Demography
- Medical Condition
- ? Ulcer
- Surgery
- Signature**

*Please sign the e-CRF using the tablet PC (or your mouse)*



- Login
- Mails
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Help

on line

# real life example

## Tablet PC in transmural care

- ◆ Academic Hospital Maastricht
- ◆ general practitioner, specialist and nurse visit patient at home
- ◆ target patient group: elderly people having problems visiting the hospital
- ◆ preventive health care

# real life example

## old situation

- ❖ collect relevant data from paper records and hospital system (status and medication)
- ❖ visit patient
- ❖ update information
- ❖ letters to specialist and GP



# Meanwhile...

## old situation

- ◆ GP visits patient
- ◆ write letter to specialist
- ◆ Specialist sees patient
- ◆ write letter to GP
- ◆ update information







# real life example

## Tablet PC in transmural care

- ◆ central database
- ◆ digital form: traditional look
- ◆ home visits using tablet PCs
  - all patient data available
  - all patient data editable
- ◆ automated reports
  
- ◆ cardiology
- ◆ geriatric care
- ◆ HIV/AIDS



# Conclusions

data collection



# Conclusions

data collection

EDC

improvement data quality

time saving



# Conclusions

data collection

EDC

improvement data quality

time saving

Mobile computing

access to data, anywhere,

anytime





# Conclusions

data collection

EDC

improvement data quality

time saving

Tablet PC

the best of Mobile computing

Mobile computing

access to data, anywhere,

anytime



Thank you for your attention !