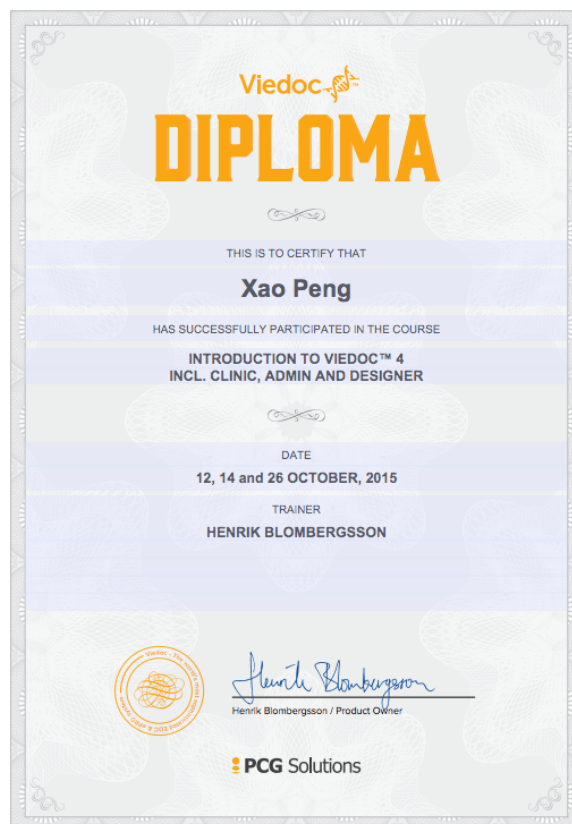## Welcome, goal and setup

1 Goals

- Welcome to study build training in Viedoc!

  The purpose of the training is to make you familiar with the Viedoc platform and all its components. After a completed training you should be able to:

  • perform a study setup on your own using the guidelines and templates provided

  • know where to look to find information about the system

  • know who to contact in case you need technical support

  After completing the training, including the mandatory home assignments, you will receive a diploma to confirm you are a certified Viedoc study builder.

Viedoc

DIPLOMA

THIS IS TO CERTIFY THAT

Xao Peng

HAS SUCCESSFULLY PARTICIPATED IN THE COURSE

**INTRODUCTION TO VIEDOC™ 4
INCL. CLINIC, ADMIN AND DESIGNER**

DATE
12, 14 and 26 OCTOBER, 2015

TRAINER
HENRIK BLOMBERGSSON

Henrik Blombergsson / Product Owner

PCG Solutions

2 Audience

- Anyone that needs to be able to manage study build / setup and configuration of a study in Viedoc should take this training. There are no prerequisites for participation although it might be helpful if you have worked with similar tasks before in other systems.

3 Setup

- The training is divided over three sessions with a couple of days in between. This allows you to spend time on the home assignment that is handed out after each session. The home assignment needs to be <u>completed and returned</u> before the start of a new session.

  There is also time set aside to answer any questions you might have on the platform. To make the training as efficient as possible, please email your questions before the start of a new session.

Agenda

1 Summary of each session

- Session # 1 (90 minutes)

- Overview of Clinic *
- Overview of Admin
- Overview of Designer
- Introducing the system roles
- System documentation (eLearning)
- Element types
- Concept of Events and Activities
- Setup of small study (home assignment)

this section can be skipped if you have used the system before

- Session # 2 (90 minutes)

  - Feedback on home assignment
  - Questions and answers from session 1
  - Version management (version/revision)
  - Modifying form contents on visit level
  - Visit window
  - Visibility conditions on form level
  - "Complex" edit checks
  - Setup study # 2 (home assignment)

- Session # 3 (90 minutes)

  - Feedback on home assignment # 2
  - Questions and answers from session 2
  - Export / Import Designs
  - Roadmap
  - Appointing the local expert(s)
  - Summary / Certification

Summary and next step

1 Summary of session # 1

- You should now have received a brief introduction of Viedoc Clinic, Admin and Designer.

  What will happen next is that you will receive an invitation to a training environment. The invitation is sent to your email address. With the invitation you are able to create your user account. The account will give you access to a demo study in Clinic with different roles. The account also gives you access to Admin and Designer so you can start building your own projects.

  A good advice before starting using the system is to go through the documentation that is available.

  User Guide - Click to open in a new window

2 Coming up

- In preparation for the next session we want you to perform a home assignment and complete that before next session starts. Please go to the next chapter for more information regarding the home assignment.

Home assignment I

1 Description

- The assignment consists of creating a small study with two forms and two visits (apart from the start visit). Follow the steps 1-10 below to complete the assignment.

  The study should have the following configuration:

  In Admin:

  • The name of the study should be your name, e.g. "Henriks study"

  In Designer:

  • Forms: Demographics (DM) and Vital signs (VS)
  • Visits: Add subject (START), Screening (SCR), Visit 2 (V2)
  • Roles: Investigator and Data manager
  • Study settings I: Selection view settings (Sex and DOB)
  • Study settings II: Patient ID settings (SCR-SiteID-PatientID###)

2 | Form 1

- Create a "Demographics" form containing 4 variables;

  - Date of informed consent
  - Gender
  - Date of birth
  - Age (derived)

  Use the eLearning to find out how to calculate the age.

Demographics

Date of informed consent | Gender
| ◉ Male ◉ Female

Date of birth | Age
| years

3 | Form 2

- Create a "Vital Signs" form containing 5 variables;

  - Were vital signs performed?
  - Date and Time
  - Systolic bp
  - Diastolic bp
  - Temperature (allowing one decimal)

- Add a data check for the diastolic variable checking that diastolic is less than systolic. [VSSYS > VSDIA]

- Add a data check for the temperature variable checking that temp is between 36.5 and 38 [VSTEMP >=36.5 && VSTEMP <=38]

- Don't forget to add the visibility conditions.

Vital signs

Were vital signs performed? | Date and time
◉ Yes ◯ No | ▼ dd MMM yyyy HH:mm 🗓 🕐

Blood pressure
Systolic | Diastolic
mmHg | mmHg

Temperature
⁰C

4 | Study workflow

- Study start: Add a visit "Add subject" with ID "START". Add the demographics form to this visit

- Scheduled visit # 1: Add a visit "Screening" with ID "SCR", add the vital signs form to this visit

- Scheduled visit # 2: Add a visit "Visit 2" with ID "V2", add the vital signs form to this visit

5 | Roles

- Role 1: Enable the Investigator role

- Role 2: Enable the Data Manager role

6 | Study settings

- Selection view settings: Map the first variable to the gender avatars and the second to the date of birth question

- Patient ID generation settings: Create a patient ID with a prefix "SCR" followed by a two digit site number and a tree digit patient number

7 | Publish

8 | Add a site in Admin

9 | Assign the design in Admin

10 Invite yourself to Clinic and test the setup

- When you think your study is ok, invite your trainer as study manager and designer to your study.

![e] Summary and next step

1 | Summary of session # 2

- You have just done your first setup in Viedoc. The key to success is to repeat this process many times.

  Some things to consider to make you an even better user of the platform:

  • Understand when to use the *fully customizable version* or the *revised version* when creating a new version of your design.

  • Create good templates and reuse them in future studies.

2 | Coming up

- Today's session covered visibility conditions, both on form and visit level. We have also discussed how to set a visit window for a visit and how to hide a question on a specific visit. These are things that you will now try out yourself in home assignment # 2.

  Please check next lesson for more details.

![e] Home assignment II

1 | Description

- The assignment consists of updating your existing study with additional forms and conditions. Follow steps 1-10 below to complete the assignment.

  Start by duplicating your design to a new fully customizable version.

2 | New form: Pregnancy test

- Add a new form according to the screen shot to the right.

  Add an edit check for the date variable; "Date of pregnancy should be after date of informed consent"

```
var a = START.DM.DMICDAT;
if ( !a || !PTDAT)
return true;
else return (PTDAT >= date(a));
```

3 **New form: Visit status**

- Add a new form according to the screen shot to the right.

Visit status 🆔 VSTAT

Is the subject continuing to the next visit?
🆔 VSTATYN
⦿ Yes ◉ No

4 **New form: Adverse Events**

- Add a new form according to the screen shot to the right.

  Use the eLearning to find out how to add an auto-counter in common events and add that script to the AENO variable in the form.

Adverse event 🆔 AE

AE No. 🆔 AENO   Event description 🆔 AEEVENT

Start date 🆔 AESTDAT   Ongoing 🆔 AEONG   End date 🆔 AESPDAT
                        ◉ Yes ◉ No

5 **Study workflow - add forms and visibility conditions**

- Add the pregnancy form and visit status form as separate activities on the screening visit.

  Add visibility conditions for:

  • the **pregnancy activity** - should only be visible for female patients
  • **Visit 2** - should only be visible if question in visit status form on screening is yes

  Finally, hide the temperature variable in the Vital Signs form on Visit 2.

6 **Study workflow - visit window**

- Add a window for Visit 2:

  "Visit 2 should be 7 days +/- 2 days from Screening"

7 **Study workflow - Add a common event**

- Add the Adverse Event form under common events and also set the summary format:

  {AE.AENO} - {AE.AEEVENT} - {AE.AESTDAT}

  Save the workflow. Close.

8 **Publish**

- Publish your design

9 **Admin - Assign**

- Assign your design in Admin

10 **Clinic**

- Test the study in Clinic. Make sure all steps above are covered. If not, go back to Designer and create a new version by duplicating the design according to Step 1 above. Publish, Assign in Admin, Test again etc.
- Good luck!