



## The need for a Biobank @ Ablynx



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**Nanobodies® -  
Inspired by nature**

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# Outline



- Y Introduction to Ablynx
- Y The need for a Biobank
- Y Vendor selection process and decision
- Y Implementation and roll-out

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# Corporate snapshot



## Corporate

- Drug discovery and development company in Ghent, Belgium
- >300 employees

## Technology

- Pioneer in next generation biological drugs – Nanobodies®
- >500 granted and pending patents

## Products

- >30 programmes – six at the clinical development stage
- Three clinical proof-of-concepts (POCs)
- >10 new clinical programmes possible over the next 3 years

## Partners

- AbbVie, Boehringer Ingelheim, Eddingpharm, Merck & Co, Merck Serono and Novartis

## Financials

- €206M in cash at 31<sup>st</sup> December 2014



# Proprietary and partnered programmes



	Therapeutic area	Product name	Target	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Filing
FULLY OWNED	Haematology	caplacizumab	vWF	[Progress bar: Discovery to Phase II]					
	Respiratory	ALX-0171	RSV	[Progress bar: Discovery to Phase II]					
	Oncology/ Immuno-oncology	Various		[Progress bars: Discovery to Phase I]					
	Inflammation/ Immunology	Various		[Progress bars: Discovery to Phase I]					
	Ocular	Various		[Progress bar: Discovery]					
PARTNERED	Inflammation/ Immunology	ALX-0061	IL-6R	[Progress bar: Discovery to Phase II]					
		ALX-0761	IL-17F/IL-17A	[Progress bar: Discovery to Phase I]					
		ozoralizumab	TNFα	[Progress bar: Discovery to Phase I] Greater China					
		Various		[Progress bars: Discovery to Phase I]					
	Oncology/ Immuno-oncology	Various		[Progress bars: Discovery to Phase I]					
				[Progress bars: Discovery to Phase I]					
				[Progress bars: Discovery to Phase I]					
	Bone disorders	ALX-0141	RANKL	[Progress bar: Discovery to Phase I] Greater China					
	Neurology	Various		[Progress bars: Discovery to Phase I]					
Various		CXCR2	[Progress bar: Discovery to Phase I]						
Other	Various		[Progress bar: Discovery to Phase I]						

Clinically validated targets  
 First-in-class

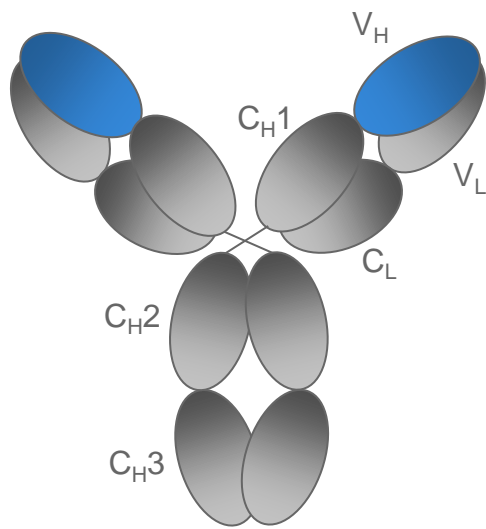
abbvie



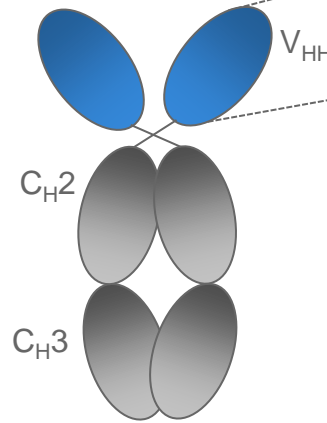
# Nanobodies – derived from heavy-chain only antibodies



- ✓ *Camelid* heavy-chain only antibodies are stable and fully functional
- ✓ Nanobodies represent the next generation of antibody-derived biologics



Conventional antibodies



Heavy chain only antibodies



## Ablynx's Nanobody

- small
- robust
- sequence homology comparable to humanised/human mAbs
- easily linked together
- nano- to picomolar affinities
- intractable targets
- multiple administration routes
- manufacturing in microbial cells

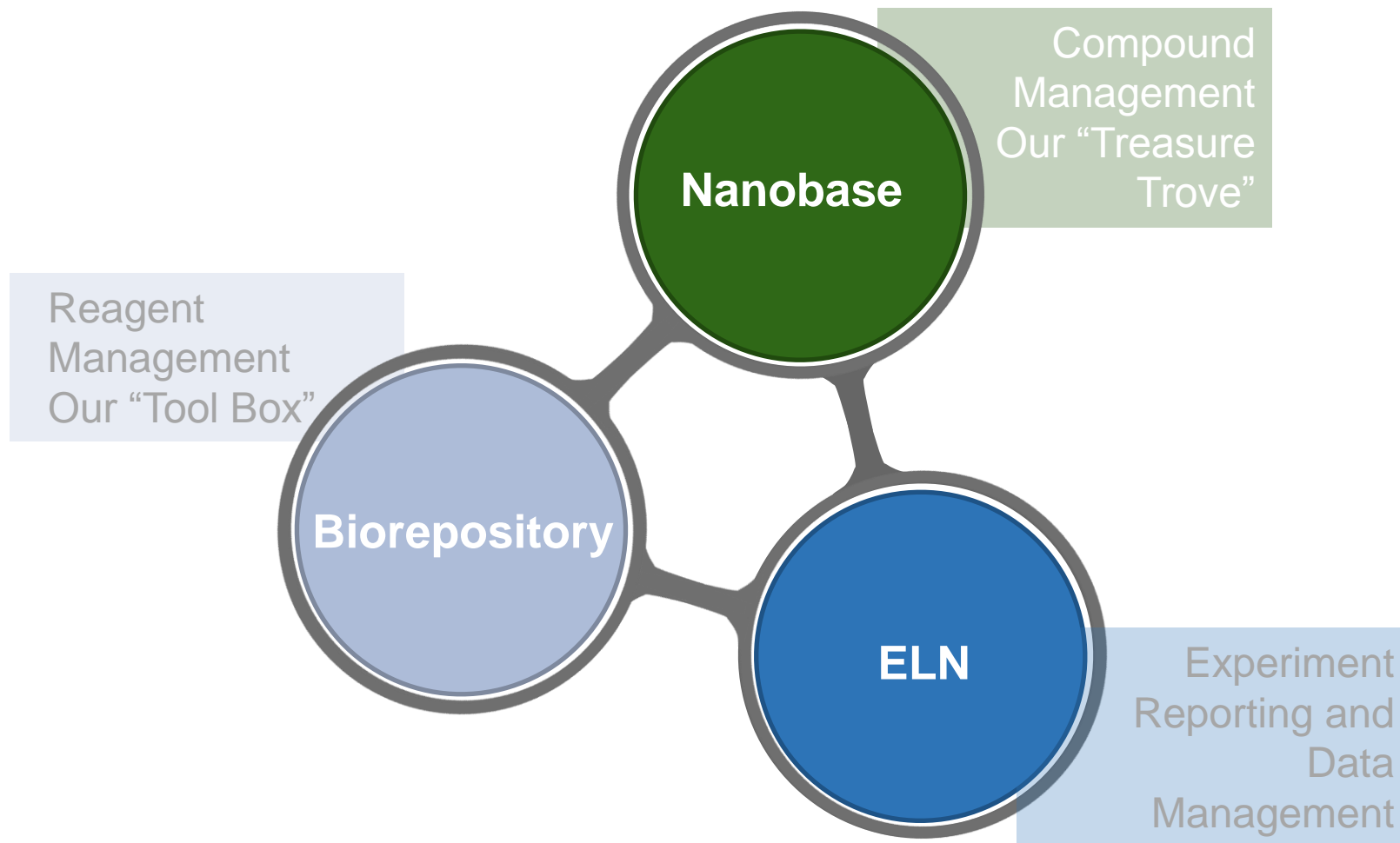
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In a biotech company, people perform experiments (ELN) on compounds (Nanobase) using reagents (Biorepository)



# Scientific Information Management @ Ablynx



## Core Systems



Nanobox (compound database)

In house developed on top of commercial tool, Main Workbench (CLC)



ELN (experiment and data management)

Commercial tool, Main Workbench (idbs)



Reagent repository (reagent management)

In house developed

## Auxiliary Systems



PatentSafe (IP Protection)

Commercial tool, PatentSafe (Amphora)



CMC LIMS (process development)

In house developed

## Data analytics



But where should we put our samples?

# Generic requirements for a Biobank



- ✔ Full compliance with regulatory and legal requirements
- ✔ Centralized database of samples which are already available (i.e. avoid possible unnecessary ordering of samples)
- ✔ Comprehensive, from cradle-to-grave tracking of all (human) tissue samples within Ablynx
- ✔ Full traceability and control of user access, i.e. who does what at what time with which sample?
- ✔ Allow us to ensure that samples are used in accordance with Informed Consent limitations and third party license restrictions
- ✔ Support for GxP
- ✔ User-friendly, time-efficient interface, preferably web-based

# Overview of human tissue sample sources

## Type I samples Commercial sources (Seralab / Tissue Solutions...)

- Legislation unclear : responsibility of purchaser to check if all regulations (IFC) were applied? Statement by vendor not always available.
- Restricted use as indicated by vendor : mostly research use only
- Donor:
  - Clinical Indications : healthy donors / donor with specific disease indication
  - Donor NOT traceable (no link to donor possible)
- Sample type: various (blood derivatives, primary cells (PBMC), tissues...)
- **>500 parental samples/year (last 3 years), currently 2500 in stock**

## Type II samples Sample Collection (Clinical Study Protocols) (CRI – Red Cross – (UZ)...) )

- Restricted use : see collection protocol / Informed consent
- Donor:
  - Clinical indication: healthy donors / donor with specific disease indication
  - Donor link possible (coded sample) via the responsible physician
- Sample type: various (blood derivatives, primary cells, tissues...)
- **> 500 parental samples/year (last 3 years), currently xxx in stock**

## Type III samples Clinical trials: GLP

- Restricted use: Clinical Study Protocol
- Donor :
  - Selected group according to clinical study protocol
  - Donor link via responsible physicians (coded)
- Sample type: primary cells, serum and/or plasma, biological specimens (e.g.sputum)...
- **2 studies per year → ~4000 aliquots per year, currently >20000 in stock**

# Outline



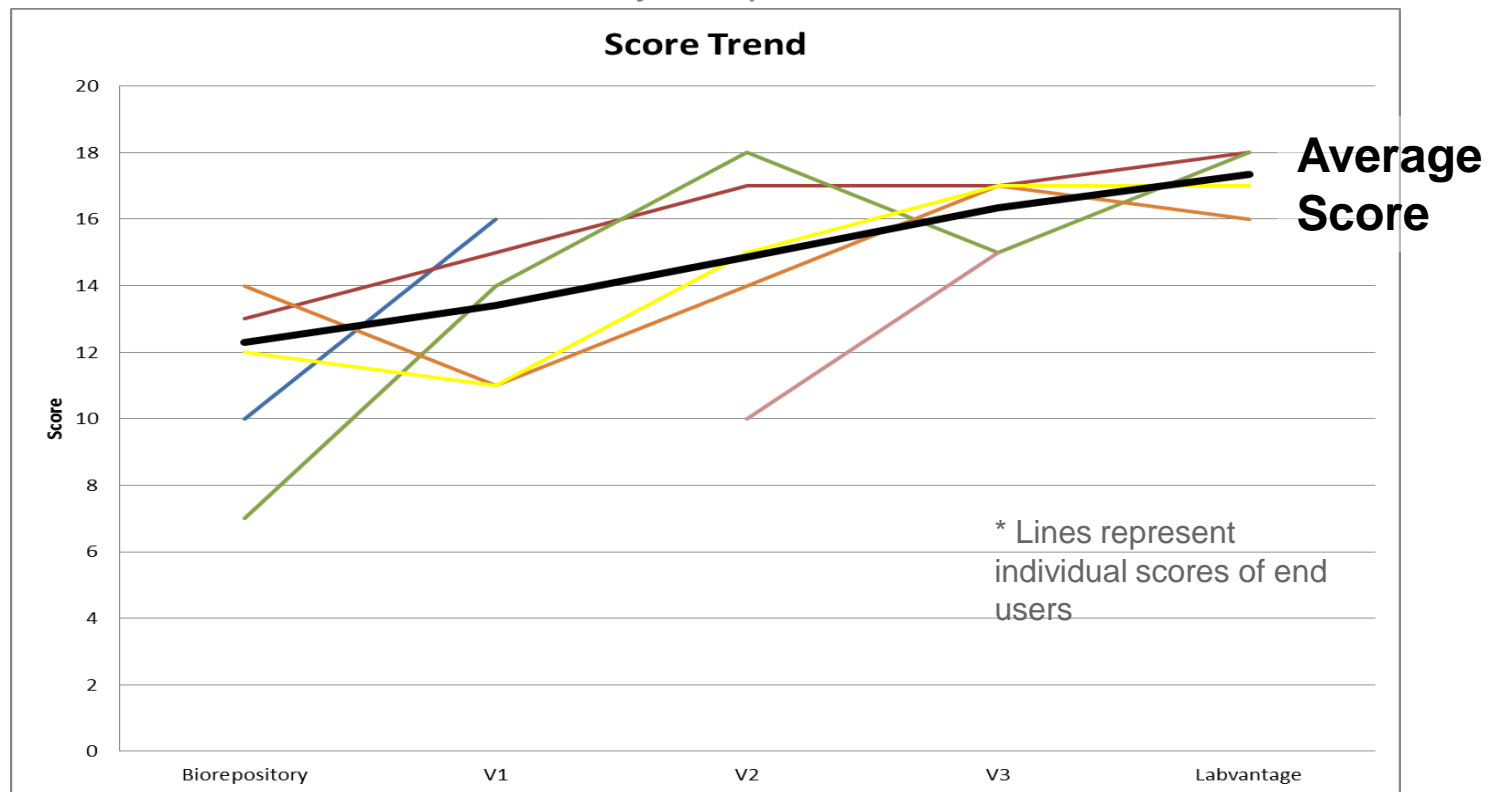
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# Vendor selection: selection strategy

- Y In-house commercial tools are no real alternatives
  - Excel
  - ELN: ELN is more suited for “one-pass” operation, such as reporting on an experiment. ‘Samples’ are not ‘experiments’, i.e. they have an ever changing life-cycle.
  
- Y Redesigning in-house developed tools (Biorepository) is not cost-effective.  
 Main gap: sample faith/traceability
  - development is more expensive than a commercial solution
  - important validation effort expected
  
- Y Open source alternatives (caTissue) were tested but found unsuitable
  
- Y Previous experiences during ELN selection process quickly gave us a LIMS shortlist
  - tip: [Laboratory Informatics Guide 2015](#) of Scientific Computing World is a good starting point

# Vendor selection: process

- Vendor selection process with 4 major commercial solution providers by involved R&D departments.
  - Pharmacology and Discovery end users constituting the Core Team involved in vendor demo
  - different vendors were scored by ~ 8 persons each



Average Score

12.3

13.4

14.9

16.3

17.3

- ✔ Selection process decision fully endorsed by higher management
  - crucial for successful implementation
  - need for biobanking solution also requested by legal department
  - well conducted vendor selection process by Core Team
  - overall consensus within the Core Team w.r.t. the preferred solution

In May 2013, Ablynx made the executive decision to use LabVantage as biobanking software system



# Outline

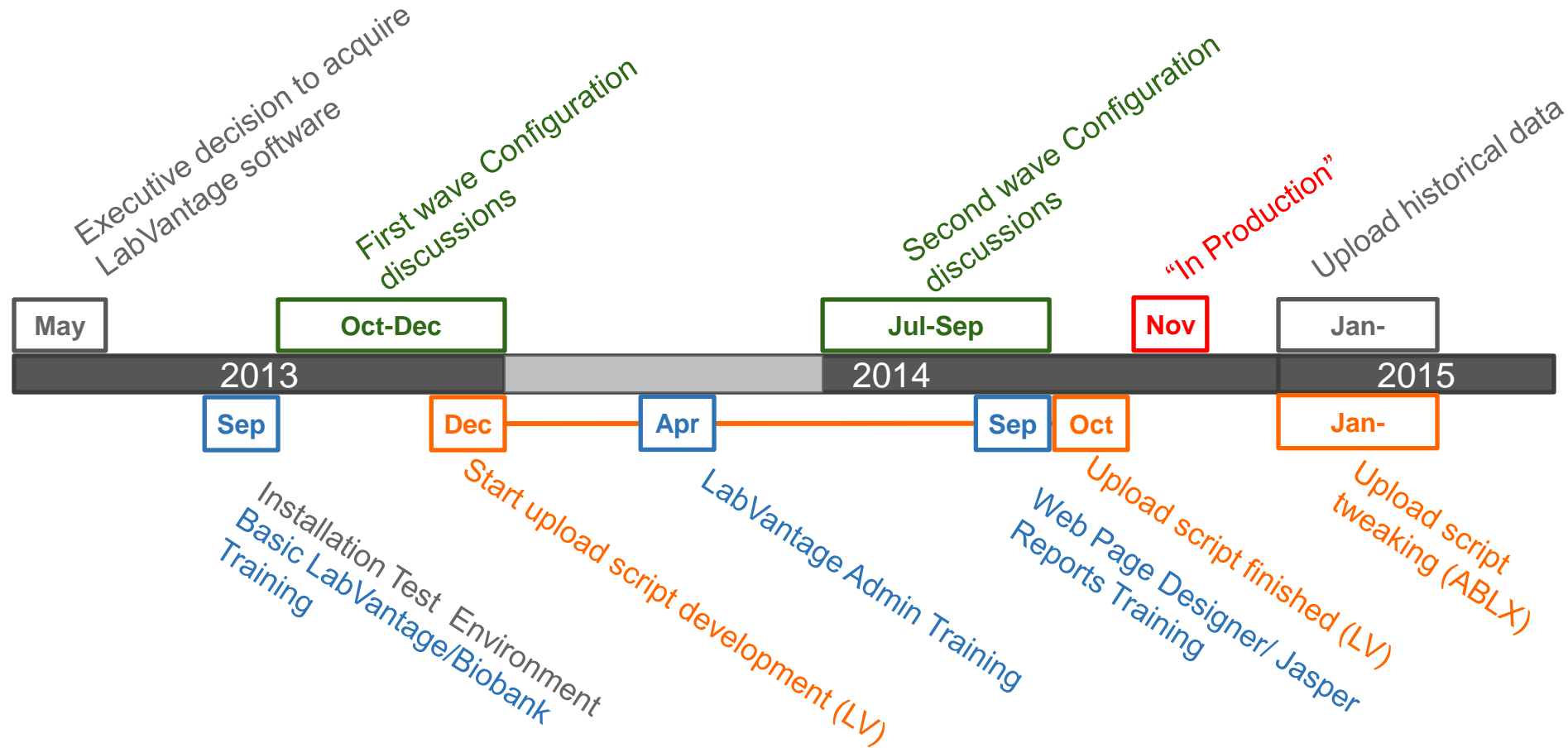


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# Implementation and roll out

- Y Basically 2 ways of doing the roll-out:
  - project lead in the hands of LabVantage
    - when the Biobank needs to be delivered on time
    - out-of-the-box functionalities are very close to the requirements and require little configuration
    - system will be used as a black box
    - Focus of the project is on vendor understanding the needs of the customer “give a man a fish”
  - project lead in the hands of the customer
    - mastering LabVantage needs some efforts and resources
    - there is the need to tweak the system in order to fulfill some more exotic wishes
    - customer wants to gain a deeper knowledge into the inner workings of the system
    - Focus of the project is on vendor training the customer, “teach him how to fish”
- Y LabVantage is very flexible on adapting to the customers needs
- Y Ablynx chose the latter strategy

# Roll-out: timelines



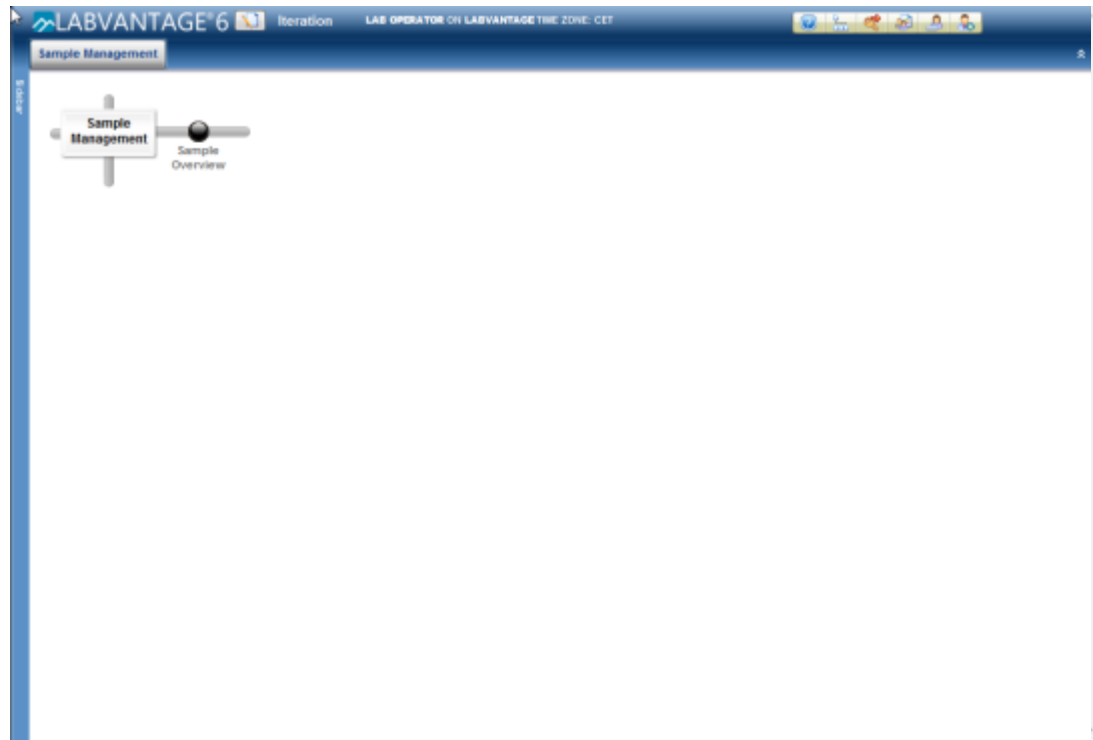
## Roll-out: user roles

### Y Bottom line: keep it as simple as needed for the end user

- restrict number of tramlines/tramstops
- restrict number of properties (i.e. Columns)
- restrict number of actions (i.e. Buttons)
- restrict security and access control limitations

### Y Three roles:

- System Administrator (T&IM)
- Lab Administrator  
→ corresponds with existing roles within the company
- Lab Operator



## Roll-out and implementation: lessons learned

- ✔ Very powerful, flexible and versatile tool, flexibility forms the heart of the system
- ✔ Project scope and focus shifted during process based on our wishes and needs
- ✔ Genuine interest of vendor in making the project a success
- ✔ In our case this is a project that is not top priority for any of the stakeholders
  - but still best to have a project leader that has it ranked #1 on his priority list
- ✔ Don't make the mistake of trying to go in production with all whistles and blows
  - after the go-live Core Team tests are more to the point
  - incremental process: gradually build up functionalities after going live
- ✔ If you go for the 'learn how to do it' approach, make sure that the trainings are early in the process
  - e.g. could have smoothed the process of creating the upload script

## The Ablynx Biobanking Core Team

- IM: Carlo Boutton, Marc Logghe, Inge Borghmans
- Discovery: Kathleen Devos, Astrid Coppens
- Pharmacology: Marie-Paule Bouche, Sigrid Sobry, Andrea Verwulgen, Valérie Lambert, Sofie Haerens, Yana Vandenbossche, Kim Legiest
- Excom, Legal Department (Maarten Goethals, Frank Landolt), IT...

## LabVantage

Michel Elshof, Hemal Rajani, Abi Chambers,  
Saumit Mandal, Rohit Kumar

You  
... for the attention

