



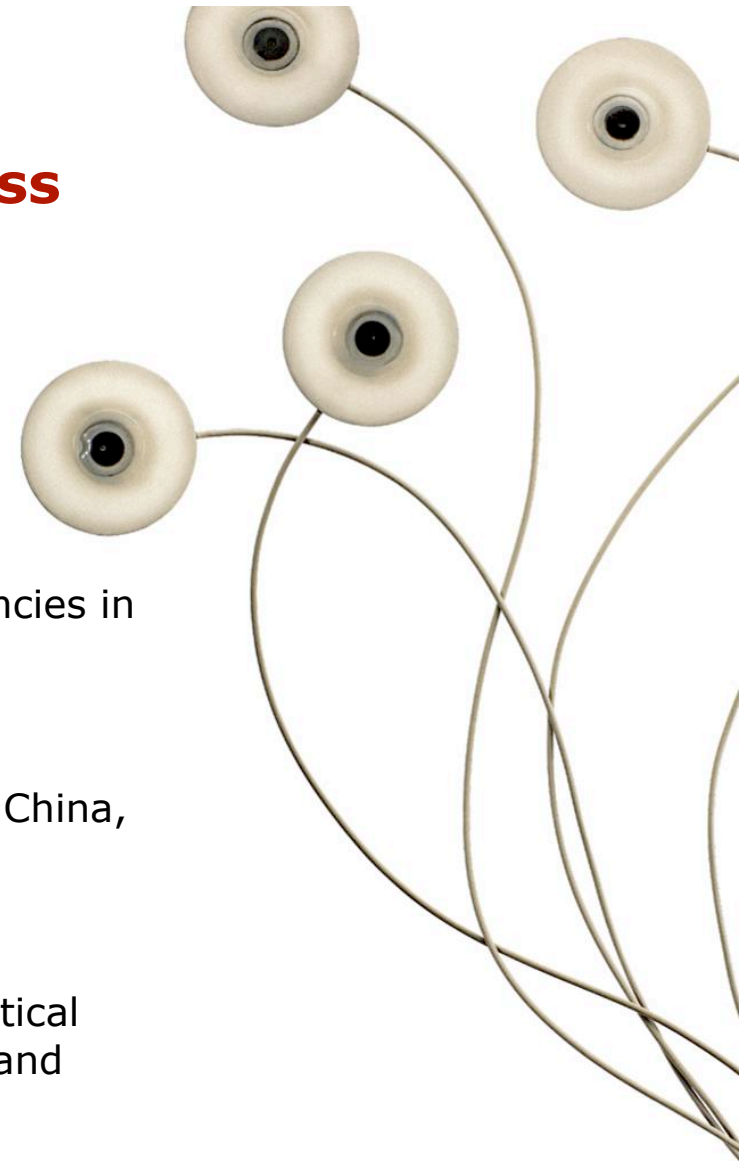
**NNIT White Paper**  
**NGP EU Summit 5<sup>th</sup> – 7<sup>th</sup> April 2011**

**NNIT**

Conscience driven. Value adding

# IT for life sciences *is* our core business

- NNIT was born as an internal IT department at Novo Nordisk in the pharmaceutical industry
- 1,450 employees and one of Europe's leading consultancies in life sciences IT
- Headquartered in Denmark with offices in Switzerland, China, the Czech Republic and the Philippines
- Life science IT is our core business with complete, practical experience with the entire pharmaceutical value chain and clients world wide



# About NNIT

## - 5 Life Sciences specific Service Areas

		<b>iDD</b> <b>Integrated Drug Development</b>	<b>iDRA</b> <b>Integrated Drug Regulatory Affairs</b>	<b>iPM</b> <b>Integrated Pharmaceutical Marketing</b>	<b>iQM</b> <b>Integrated Quality Management</b>	<b>iPP</b> <b>Integrated Pharmaceutical Production</b>
<b>Strategy</b>  <b>Design/Transition</b>  <b>Operations/Continual Improvement</b>	<b>Initiation/Analysis</b>	Maturity Assessments Business Cases Programme Initiation IT strategy	Maturity Assessments Business Cases Programme Initiation IT strategy	Maturity Assessments Business Cases Programme Initiation IT strategy	Compliance Assessments Quality Management Framework Business Cases	Business Cases IT strategy
	<b>Project Services</b>	EDC/CDMS CDW/SCE Safety Standardisation CTMS Portals	ECM eSubmission Portals PIM Global labelling	Pharma operational CRM Pharma analytical CRM Sales performance reporting	Project Quality Management QM framework QMS SOP's Audits	LIMS Environmental Monitoring
	<b>Application Management</b>	Application support Outsourcing services Off-shoring	Application support Outsourcing services Off-shoring	Application support Outsourcing services SaaS	QM outsourcing QMS support and maintenance	Application support Outsourcing services Off-shoring

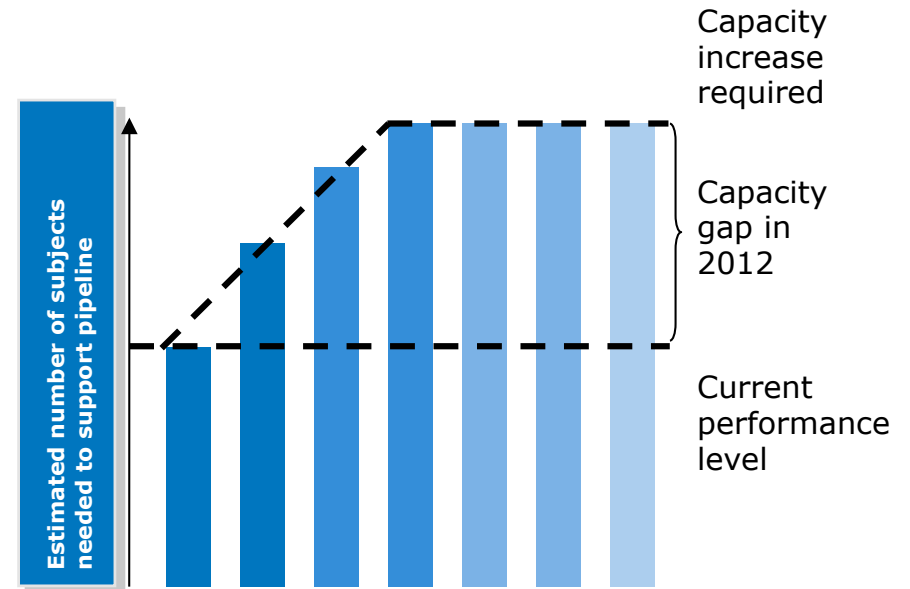
# Integrated Drug Development - Rationale and business drivers

Clinical development organisations are under increased pressure to support more clinical projects, perform more trials, with more patients, collecting more data to support pipeline.

Hakan Björklund, CEO Nycomed: „The more stringent regulatory environment and related demands for more supportive data on experimental drugs are making matters more difficult, extending the time it takes for drugs to come to market and effectively reducing the amount of time they are protected by the patents which companies rely on to claw back their investments“. The cost of bringing a new drug to market currently runs at more than \$2 billion, according to analysts at Bain & Co.

Available options to increase capacity:

- More staff
- More outsourcing
- Increased efficiency



## Integrated Drug Development

- Streamlined and simplified business processes across Clinical Development
- Higher degree of automisation and standardisation
- Increased collaboration and information sharing internally and externally

**Shorten time to market, increase efficiency, increase compliance**

# Integrated Drug Development

## – Defining the Journey through an eClinical project

Organisations develop over time, and as resources both financially and in terms of staff become scarce, a new approach to clinical development has to be implemented allowing companies to increase capacity and through-put via more efficient and adaptable working processes.

### What We Are Coming From

- A functional view of the world
- Multiple systems with manual support
- Management on a project-by-project basis
- Individual effort
- One-off creativity
- Islands of information



### What We Are Going To

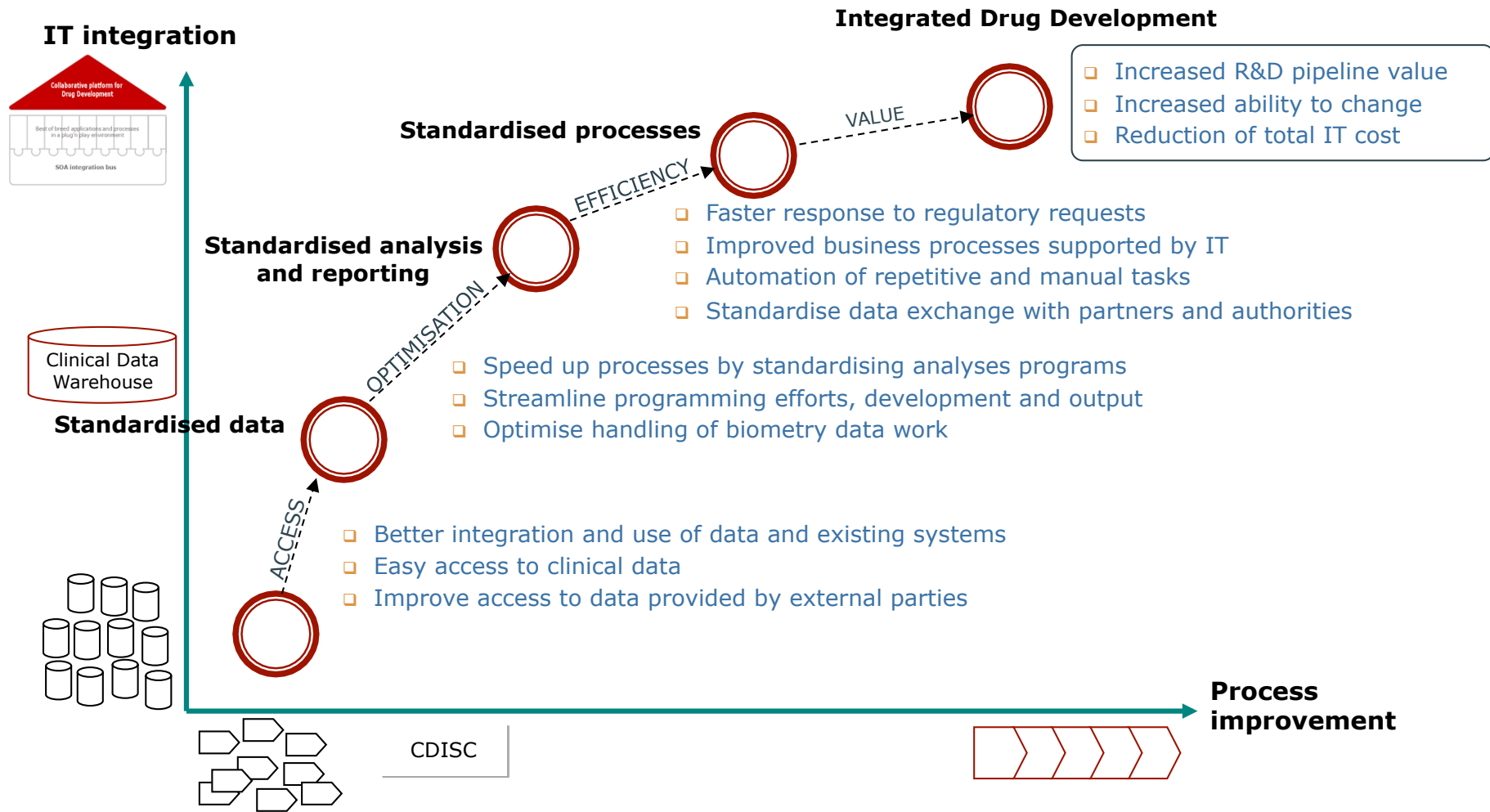
- A process view of the world
- Standard automated processes and integrated systems
- Management of a pipeline of products
- Combined efforts of multiple skill sets
- Easy access to information across functions and processes

### eClinical Programme Vision – Integrated Drug Development

- The eClinical approach to R&D processes and IT systems is to rethink the Drug Development landscape (applications and processes) in order to define a larger vision and architecture, develop new and improved processes based on identified improvement potentials and a comprehensive road map for execution
- The point is to move away from silo-oriented legacy systems, towards a modular architecture based on web browser access across organisational and geographical areas.

# Integrated Drug Development

- The journey that leads to the realisation of the Vision



# Reference case, Integrated Drug Development – Benefit impact from an eClinical programme

The eClinical Programme has the potential to shorten **>240 days per project** (critical path days) – and other time-savings (non-critical path) to **>120 FTE days /project**

