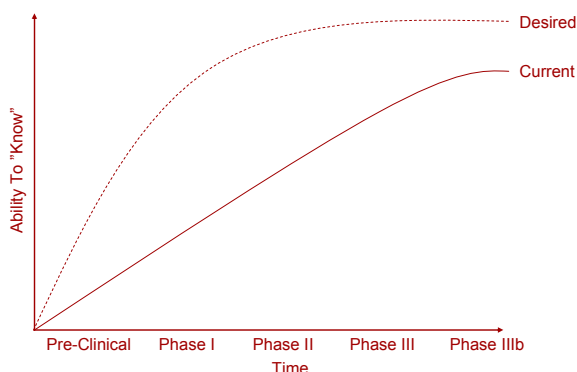


# Process and IT Optimisation in Clinical Development

## eClinical

### Why eClinical?

The need for a streamlined global R&D organisation has never been more urgent for pharmaceutical, medico and biotech companies. Typically, business processes and IT have been sub-optimised and too inefficient to meet this requirement.



Pharmaceutical companies need to close the gap between desired knowledge and the current information available, in order to:

- Improve decision making
- Reduce time to market
- Reduce late-stage attrition rate
- Improve early kill rate

### NNIT's eClinical concept

NNIT has developed eClinical, a method that enables pharmaceutical companies to study their existing business processes, improve them, and integrate underlying systems to support the new optimised processes.

By integrating systems and optimising the capture and use of clinical data, eClinical enhances the global integration of pharmaceutical business processes.

eClinical allows you to find and improve the key goals, drivers and Critical Success Factors (CSFs) for your company. By creating greater efficiency and benefits, you enhance the value of your pipeline and your company.

The method consists of three phases:

- Phase I – Analysis
- Phase II – Planning
- Phase III – Execution

### Phase I – Analysis

The objective is to define the scope, timing, content, deliverables and approach for Phase 2.

The main activities are:

- Interviews to assess areas that are most likely to benefit from improved processes and IT systems

- Identify CSFs, opportunities, enablers and benefits

### Phase II – Planning

The objective is to define business cases for each implementation project. The business cases must include the quantifiable benefits and costs of both implementation and operation.

The main activities are:

- Analysis and documentation of 'as-is' processes
- Analysis and documentation of 'to-be' scenarios
- Identification of IT enablers for opportunities mapped to processes
- Documentation of business cases for each opportunity

### Phase III – Execution

The objective is to implement the identified changes to business processes and IT support.

The main activities are:

- Specification of changes
- Vendor selection
- Design and implementation
- Change management
- Roll-out

### Why NNIT?

NNIT is a leading provider of IT services in the European market, with sustained financial growth. We have more than 950 employees in offices in Denmark and Switzerland.

Our competencies cover:

- Subject matter experts within pharmaceutical business processes
- Business process consultants with domain knowledge of pharmaceutical business processes
- Project managers
- Change managers
- QA managers
- Application specialists
- Certified technical specialists

Our quality management system complies with FDA validation requirements for computerised systems and ICH GcP. Our problem management system and CMMI certification ensure that all issues are resolved quickly and effectively.

### Further information

Please contact us at [nnitcontact@nnit.com](mailto:nnitcontact@nnit.com) for further information.

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