



Developing a Roadmap for a European Healthgrid

Ethical, Legal, and Socio-economic issues

mapping ELSE issues on a roadmap for HealthGrids

- ▶ Celine Van Doosselaere, EHMA
- ▶ Karl Stroetmann, empirica
- ▶ Petra Wilson, Cisco IBSG

The Share project (FP6-2005-IST-027694) is funded by the European Commission Information Society and Media DG under the 6th Framework Programme.



<http://www.eu-share.org>





• Ethical, Legal, and Socio-economic Work Package tasks

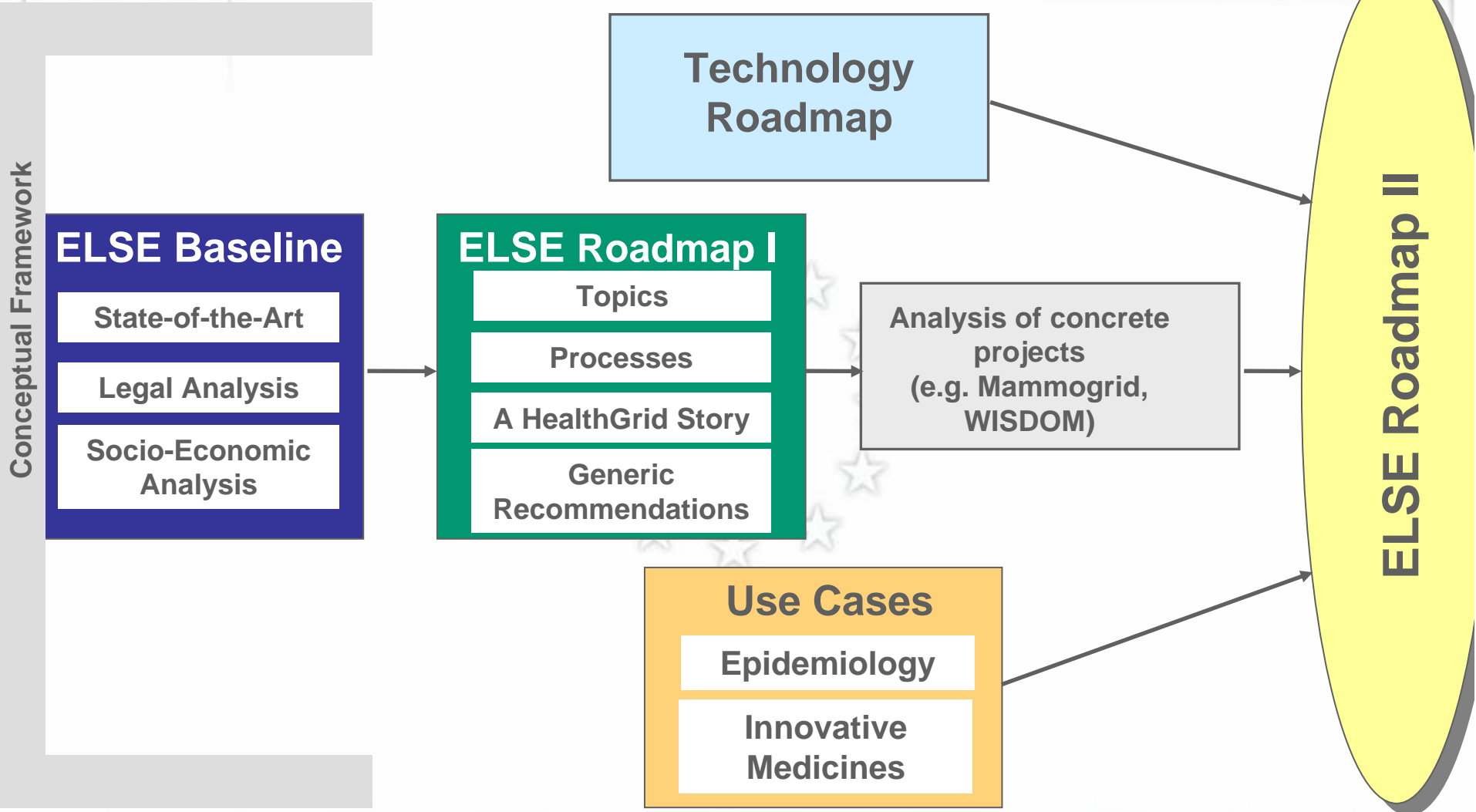


- To investigate how Grid computing in healthcare can comply with **existing EU level legal rules** which regulate the collection, storage and manipulation of personal data
- To outline how the observance of these rules and regulations is/can be built into the **organisation of health research and delivery**
- To outline how a **good economic business case** can be made for Grid computing in the health sector based on a cost-benefit analysis of Grid computing in the health sector.





Developing the ELSE Roadmap - a Process View



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• Economic Analysis



- Addressing prime objectives of the healthcare system
- Key Actors in Healthcare Systems / Payers, beneficiaries
- Applying the *eHealth IMPACT* methodology
 - identifying all relevant costs:
 - ▲ **investment costs** (initial and replacement costs for ICT hardware and software, and costs of process and organisational change)
 - ▲ **operational costs** (of running the service)
 - identifying all major benefits (**quality, access and efficiency**) for all stakeholders: citizens/patients, healthcare provider organisations, and third party payers





• Economic Analysis - cont.



- measuring:
 - ▲ **net economic gains** (economic values of direct benefits minus identified costs)
 - ▲ **eHealth utilisation** (usage of the service that is supported by ICT)
 - ▲ **productivity** (changes in the unit cost of the service)
- through three periods:
 - ▲ **planning and development**
 - ▲ **implementation**
 - ▲ **routine operation**





• Economic Analysis - cont.



- Potential benefits of HealthGrids
 - **Time savings** (e.g. from faster access to database search results, value calculated using the pay rate of staff doing the search)
 - **Access** for professionals to larger, or joined, clinical and research databases for clinical purposes
- Potential economic bottlenecks
 - lack of (knowledge about) private incentives
 - business case for the routine use of grid technologies





• The Socio-economic issues



Social issues (incl. organisational, cultural, policy):

- ▲ Change management
- ▲ Training for new skills
- ▲ Collaborative working
- ▲ Cross-organisational resource deployment
- ▲ Process design and new care pathways
- ▲ Acceptance by healthcare professionals
- ▲ Trust and confidence
- ▲ Awareness of decision makers
- ▲ Leadership and political support
- ▲ Policy development





• The Legal and ethical issues



- Legal issues include:
 - Data Protection
 - Liability for Goods and Services
 - Intellectual Property Rights
- Ethical issues include:
 - Beneficence
 - Non-maleficence
 - Autonomy
 - Privacy





• Legal Analysis - data Protection and Privacy



- Some issues to be considered:
 - Data Controller/ data processor
 - ▲ clarifying who has legal responsibility
 - ▲ Clarifying the role and extent of patient implied consent
 - Research and Preventative Medicine
 - ▲ clarifying medical research across borders
 - ▲ harmonizing divergent approaches
 - Genetic data
 - ▲ establishing EU rules on processing genetic data
 - Network Security
 - ▲ Clarifying boundaries of liability





• Legal Analysis - Product and Services Liability



- Some issues to be considered:
 - Product Liability
 - ▲ clarifying general principles - is this enough?
 - ▲ differentiating between professional or general use
 - ▲ establishing guidelines on contract terms establishing EU rules on processing genetic data
 - Services Liability
 - ▲ Establishing EU guidelines or legislation
 - Medical Devices
 - ▲ Clarifying the application of Medical Devices law to healthgrid components.





• Legal Analysis- Intellectual Property Rights



- Some issues to be considered:
 - Sui Generis Data base Protection
 - ▲ clarifying general principles of Sui Generis - sufficient for healthgrids?
 - Protecting the IPR in the Grid Application
 - ▲ Clarifying the extent of the Computer Programmes legislation -sufficient for healthgrids?
 - ▲ Exploring the role of open source licensing (Reasonable and Non-Discriminatory terms (RND))
 - ▲ NB - to be re-opened during 2007





Summing up



- Current status: Roadmap I being finalised
- Next steps:
 - Mapping onto 2 use cases:
 - ▲ Epidemiology
 - ▲ Drug discovery
 - Roadmap II

