

Ownership of Intellectual Property Rights in Medical Data in Collaborative Computing Environments

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The IMaGE Project

Intellectual property rights in
Medical data in
a
Grid
Environment

eDiaMoND

- A large interdisciplinary eScience project
- A collaborative platform for sharing medical data
- In the context of breast cancer prevention
 - The UK National Breast Screening Programme
 - Sharing the clinical workload
 - Facilitating new kinds of scientific research
- Acquiring medical data was critical

NHS

Breast screening clinic

University

The Grid



screening



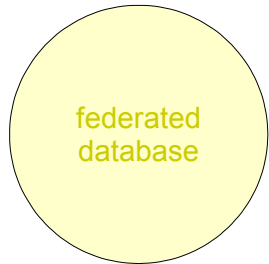
scanning

data entry

annotate



upload



federated database



patients



patient cases



encrypted dvd

“We initially said to [our] lawyers, 'who owns the data?', and they never came back with an answer!”

(eDiaMoND Team Member)

“If the NHS want to adopt PACS [Picture Archive and Communication Systems] and all digital systems, and the concept of joined up health care, then they haven't addressed some of the fundamental issues, which is, who actually owns the medical record?”

(eDiaMoND Team Member)

Approach

- Retrospective Study of the eDiaMoND Project
- Interviews with key stakeholders groups
 - Clinicians, Researchers, Patients, Ethics Committees
- Jurisprudential Research
- Modelling
- Evaluation

Legal Concerns

- The Formal Intellectual Property regime
 - Copyright
 - Database rights
 - Patent law
- Law of Contracts
 - Codes of Conduct, Tort liability, Employment Contracts
- Personal and Human Rights

I: “Well what about the data in your database, do you own that data?”

E: “The cautious assumption we've made is that we don't own it, but we're licensed to use it; in some cases an explicit licence from [one site], and in others and implicit license. ...but we don't believe that we have the right to go and sell it, and we can't do anything above the two years of the project anyway.”

(eDiaMoND Team Member)

- Acquiring medical data was challenging
 - Ethical approval
 - Use of data granted for a specific purpose and duration
 - Contractual agreements with participating clinics
 - Copyright concerns

E: “The other big problem for us, with regards to the epidemiological stuff and collecting mammograms, is that our connection with [the epidemiologist] didn't really materialise... Although she was happy for us [here] to digitise them for her, she wasn't particularly excited about the idea they would go into some Grid database that might be accessible, you know, you never know quite what's going to happen to the data at the end of the project. She felt quite, it's obviously quite valuable data, and she'd like to keep control of it, I suppose.”

I: “Do you think that's protecting all the effort she's put into acquiring that data?”

E: “Yeah, yeah, I think that's exactly it. Having put in all that effort, I guess she feels that she wants to have sole right to publish anything.”

(eDiaMoND Team Member)

- Data can be extremely valuable
 - Datasets are gathered for teaching or research
- Researchers / Clinicians expect to reap the benefits of their efforts
- Licensing agreements for use of data
- Changes in a Digital World?
- Database rights

I: So would you have to go through the same sort of contractual rigmarole and agreements to share that corpus of cases with [another hospital] as you have [for eDiaMoND]?

C1: No... there are specific professional guidelines that we all work to about research and research data and I suppose we're more comfortable sharing with other health professionals because we realise that there are specific rules, whether they're written or not, they're there, or codes of practice is perhaps a better way of putting it.

I: Culture and codes of practice?

C1: Culture and codes of practice, absolutely

C2: and the [General Medical Council] and the codes that cover the way we work, we need to be ethical and expect everyone else to be the same

C1: Which are not there in private companies. ((C2 and I laugh)) Well they're just different, I'm sure they're there, they're just different, and that's perhaps why with private companies we need these slightly more formal contracts.

(Clinical Staff associated with eDiaMoND)

- Formal Contracts are not always necessary
 - But even implicit contracts have a legal status
- Intellectual property most relevant at the interface with commercial organisations
 - Healthcare and private enterprise are inextricably linked

Project Goals

- Develop a UK-based intellectual property ownership model for the sharing of digitised medical data in a collaborative computing context.
- To ensure that society receives maximum benefit from medical data, while respecting the rights of those who may have a stake in its use, distribution or commercial exploitation.