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Ownership of Medical Images in E-Science Collaborations: Overture or Central Plot?

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7.1 Ownership of Medical Images in e-Science Collaborations: Learning from the Diagnostic Mammography National Database

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Understanding the Soft Infrastructure of e-Science

The global e-science infrastructure enabled by Grid technology holds the promise of a technically complex supercomputing infrastructure, distributed among geographically disparate locations and providing increased processing power and data storage.

Technical complexity is one thing; legal and social complexities are another. Although less tangible, the latter can be as difficult to isolate, analyze, and manage as engineering technologies. This essay suggests that as much attention should be paid to this "soft" normative infrastructure of e-science as to its "hard" physical counterpart. Otherwise, the promised benefits of Grid collaborations may not be fully realized. The essay illustrates this view through analysis of a case study[1] of the electronic Diagnostic Mammography National Database (eDiaMoND) pilot project, a £4.25 million inter-disciplinary U.K. collaboration aimed at creating a database of digital mammography images using Grid technology.[2]

An Exemplar of Key e-Science Issues

The eDiaMoND project promised much: as a training tool, it would reduce regional disparities in diagnosing breast cancer, would improve surgical results by providing high-quality images to surgeons, and would be used as a research tool to enhance epidemiological and research knowledge. All three areas carried the eventual promise of internationalization.

As well as linking geographically dispersed users and physical collections, eDiaMoND connected institutions with widely differing mandates, funding sources, and internal norms. Distinctive features of this project were network members' coequal status, its promise of a grand virtual research infrastructure, and the novel use of Grid technology to effect this infrastructure. It would not merely provide a database of digital mammograms, but would also create a community of e-researchers. It therefore offered fertile ground to examine the soft infrastructure of e-science.

Evaluating Image-Ownership Aspects of eDiaMoND

The case study evaluating eDiaMoND was conducted by examining the legal relationships between the parties, focusing specifically on the intellectual property rights (IPRs) in databases and images in the project. Among other things, IPRs function as tokens that commodify and define veto rights between the parties. IPRs can also be used to generate financial rewards for their holders. Intellectual property law differs from corporation law, which defines the internal structures of organizations, and from the law of confidentiality and privacy, which helps determine relationships with third parties such as patients. IPRs directly engage project collaborators by artificially creating scarcity and forcing them into relationships of sharing, conflict, trust, and suspicion over how those tokens are created, distributed, and exploited for profit.

The study team hypothesized that just as property relationships lie at the root of the social contract and the modern state, IPRs may similarly lie at the root of the e-science community and its future organization. Therefore, the study researched instantiations of norms of intellectual property—mainly copyrights and database rights—between the parties, ranging from formal (e.g., legislation and contracts) to informal (practices and custom). No separate corporation was created to further eDiaMoND's purposes, and few written documents were concluded between the parties. Norms had to be deduced from institutional policies and procedures, governmental policies, and practices evident from interviews of participants.

Case Study Findings

The study on which this essay is based found that

1. Public U.K. National Health Service (NHS) Trusts[3] probably retained ownership of intellectual property in the physical and digital mammograms;
2. The commercial partners had an implied license for limited use of the images during the course of the development of eDiaMoND, but would not necessarily retain rights to use the mammograms after eDiaMoND ended;
3. Noncommercial eDiaMoND participants similarly had use rights in the images for the duration of the program but did not have reuse rights (largely because of the ethical clearances that would be required); and
4. NHS Trusts, universities, and some other participants retained and gained some database rights and copyrights in databases used in and created under eDiaMoND's aegis.

More legal certainty and coherence between the parties might have been achieved through written agreements that focused on the allocation and use of IPRs. Creating a separate legal identity for eDiaMoND and channeling contracts and management decisions through that identity would have provided a hub for the parties' legal relations.

Project coordinators, however, were reluctant to conclude formal contracts with non-commercial collaborators. For example, after a conflictual initial exchange of terms with one hospital, coordinators did not seek similar IPR agreements with the other hospitals. Neither did they reprioritize the exchange of contractual terms and certainty, which—much like a prenuptial agreement—they evidently thought could damage the spirit of collaboration.

Although the role that informal agreements played in nurturing the collaboration is unclear, uncertainty over IPR ownership was eventually blamed for making it impossible for the eDiaMoND collaboration to proceed past the pilot stage. Yet this stalemate seemed to have less to do with IPR ownership than with the fact that the parties could not agree on how their common endeavor should proceed. They had plainly not thought to establish Mertonian norms[4] of open science, in particular communality. The relationship could not generate norms to govern participants' conduct without common basic rules or values to guide their collaboration, not only in unanticipated situations but even in anticipated ones (such as how to proceed when the project formally terminated).

Building an Effective Technological Infrastructure and Working Culture

Although the deduced legal allocation of IPRs among the eDiaMoND parties generally met the parties' assumptions, following the law did not provide the community with the tools to evolve. Technology had allowed cooperation across great distances but had not provided the means to develop the underlying community relationships that would provide the basis of trust, agreement, and default rules. Although technology may be good at bridging physical gaps, it is not necessarily as effective in bridging social and commercial ones.

The case study therefore concluded that collaborations such as eDiaMoND should include, at their project design stage, plans for building a functioning working culture. This feature is essential where parties seek a long-term relationship and are geographically and institutionally diverse. It will be critical if a project becomes politicized with the involvement of important commercial partners and sensitive data. These challenges will magnify in international e-science endeavors, where norms of interaction may differ even more than they do within one country.

Bridging this divide may involve processes that include a range of tools and mechanisms:

1. Collaborators and project designers should spend time at the outset creating mechanisms to support relationship building, trust, and internal dispute-resolution techniques. Developing an agreed "statement of joint understanding" before concluding formal agreements might then be less polarizing. The joint statement can be attached

to the formal documents and assist in their interpretation. Community building would also create a process of informal norm development—norms that would fill in the gaps that necessarily follow formal agreement.

2. Formal contracts should be circumscribed documents defining how the parties are to proceed. Detailed rules of governance should be left to mechanisms such as negotiated codes of conduct, with penalties, rewards, and procedures that build the project community. For example, penalties might include limiting access to a peer-reviewed deliverable. Independent multistakeholder agencies can oversee governance and provide external oversight. Such work should precede the commencement of the project.

Future studies should seek to determine if e-science projects require sui generis norms of IPR governance unique to the e-science context. The allocation of and management rules relating to IPRs will be an important overture to the project—more than a sideshow, but a great deal less than the central plot.

Notes

1. In addition to the authors of this essay, the case study team comprised Marina Jirotka, Oxford e-Research Centre; Chris Hinds, Oxford e-Research Centre; Giuseppina D'Agostino, assistant professor, Osgoode Hall Law School; Charles Meyer, visiting professor of law, University of Pittsburgh; and Mustafizur Rahman, researcher in e-science, Oxford University. Results are published in D'Agostino, Hinds, Jirotka, et al. 2008.

2. The eDiaMoND project lasted two and a half years from the end of 2002 and involved a core of thirty to thirty-five staff spread over twelve locations in the United Kingdom. The participating entities included five universities, four U.K. National Health Service Trusts, a multinational company, and a rapidly expanding university spinout enterprise. Funding came mainly from the U.K. government, the U.K. Economic and Social Research Council, the private sector, and in-kind contributions from the universities and trusts. The legal and institutional background of eDiaMoND is discussed further in chapter 7.

3. NHS Trusts are responsible for the local management of health services in the United Kingdom.

4. Communalism, universalism, disinterestedness, originality, and skepticism, also known by the acronym CUDOS. First formulated by the sociologist Robert Merton (1973 [1942]).

References

D'Agostino, G., C. Hinds, M. Jirotka, C. Meyer, T. Piper, M. Rahman, and D. Vaver. 2008. "On the importance of intellectual property rights for e-science and the integrated health record." *Health Informatics Journal* 14:95–111.

Merton, R. K. 1973 [1942]. *The sociology of science: Theoretical and empirical investigations*. Chicago: University of Chicago Press.