Legal Issues

Many lives could be saved if researchers had access to large amounts of medical data during research. However, currently the National Health Service (NHS) has no computer system to anonymise and analyse patient information. My team has worked on developing such a system which first anonymises medical data by removing all identifying patient information and then analyses these datasets. In the following summary I will look at the contract agreements of our project, how we decided between different types of software licenses and finally which legal issues have to be considered when improving our current solution in the future.

An official contract was signed between the University College London computer science department, our client, a consultant radiologist at NHS, and my team as contractor team. The contract specified the general terms and conditions and stated that further contract details will be discussed and agreed between our team and the client. After multiple client meeting to clarify the requirements we agreed on the delivery, tasks and schedule for the project, specifying that a working prototype of anonymisation and analytics software will be delivered by our team on the 23 March 2018. Besides the program code, we also have to deliver a project website, video and poster, which explain how we implemented the features and how our system can be used.

Since our task was to deliver a prototype of a system, we are not liable for the correct functionality and security of our product because the client has acknowledged that the product we delivered is not complete and may not contain necessary security requirements or full functionality at this moment. This acknowledgement represents acceptance of liability by the client for any errors in functionality or possible law violations.

According to our contract, the client will own all the rights for the software and other deliverables of this project. This means that our team will not be permitted to use any materials from this contract in any future work. Since our client wants to create a low-cost solution for the NHS, we had to avoid proprietary software during the development and rely on free and open-source components.This lead us to choosing software with open-source licenses during the research and development phases. We compared three programming libraries, one with the MIT license, one with a GPL license and a proprietary solution. The proprietary solution would incur significant cost when used by the NHS and the GPL license would require us to publish our software with the same GPL license and make our source code publicly available. [1] The MIT license, however, allows us to use the library for free without any legal restrictions. [2] Since our client wants to have a low-cost solution and isn't sure if he intends to make the system open source, the MIT license was the best choice.

Data privacy is a major concern for our project since we are developing a solution for NHS which could work with real medical data and patient information. There are laws that protect patients and their privacy, so we have to make sure that patient data is protected and used appropriately in our software.
The Data Protection Act of 1998 is part of UK legislation that specifies that patient privacy has to be maintained. [3] This law requires that patient data is obtained and processed fairly and lawfully, which we are addressing by restricting data access to the NHS and only allowing researchers to access data which is relevant to their work. Our system should only process anonymous patient data at all stages in order to protect patients' privacy. No patient should be identifiable from any combination of data points in our system. To this end we have developed a data anonymisation tool which removes sensitive patient information before it is used in our analytics system.
Furthermore, the act restricts data disclosure and we are ensuring that data is secure by storing data on NHS servers and creating a secure connection between server and user. This helps prevent attacks on patient data. In addition, we have to ensure that our service maintains connectivity at all

times and potential issues and vulnerabilities are resolved in timely manner and without disrupting the use and functionality of our system.
Finally, the Data Protection Act gives patient the right to access any personal information used by the NHS. Our system should have an interface to update and delete patient data as needed. Moreover, a doctor should be able to provide a full and complete report of their data upon request.
The act also includes other data protection requirements, but these don't apply to our project and so are not addressed here.

In conclusion, our team has developed a software solution which anonymises and analyses medical data. According to our contract, the client owns all deliverables of our project and retains full control over their use. Developing software for the medical field comes with myriad legal issues, so our system has to be evaluated under many conditions to ensure that medical data is processed according to data protection laws. When our system is used by the NHS, it could help doctors to develop better treatments and save patients' lives.

References

1. The GNU General Public License v3.0- GNU Project - Free Software Foundation [Internet]. Gnu.org. [cited 19 March 2018]. Available from: https://www.gnu.org/licenses/gpl-3.0.en.html
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3. Data Protection Act 1998 [Internet]. Legislation.gov.uk. [cited 19 March 2018]. Available from: https://www.legislation.gov.uk/ukpga/1998/29/contents