Scientific Data Management in Bioengineering: a Risk Management Viewpoint

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Data created and used in research projects must be properly managed for preservation and reuse. This need led to the emergence of the concept of Data Management Plan (DMP), which details how data generated during research projects is to be handled during a project’s lifecycle. However, we believe that a number of concerns addressed in a DMP could be more elaborated, namely those that we can identify as related to Risk Management (RM). This can be especially relevant for Bioengineering, where the management of sensitive data is a frequent concern.

RM should be a process that, in an established context (organization, product production, project, etc.) aims to identify, assess and mitigate risks to an acceptable level. A risk is an identified uncertainty that we can associate with an event which, if occurring, can affect an objective. The standards ISO 73 and ISO 31000 define the main concepts of this domain, and ISO 31010 catalogues techniques that can be used for its process.

A number of concerns motivating to the definition a DMP are also usually covered in RM, which motivates the concept of a wider framework for data management in science, where a DMP might be complemented by a RM plan. This will bring new value, but also will require the clarification of new roles and responsibilities. For example, the project PI, as the accountable figure for all decision making, should be aware of its responsibilities to define the RM context and communicate risks, not only internally but also to the Project Sponsors and other those defining the highest context of responsibility of the project. The Scientific Team must be prepared to assume the role of Risk Owners, being responsible for the control, monitor and inform of all decisions regarding specific risks. Finally, a new role is required, which we can name as DM Expert, as the person in charge of the DMP, which ideally should be a trained professional for that role. He would also be a Risk Expert, competent to help defining the RM processes.

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