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Introduction of Records Management at Actelion: Concept Phase

In the past, "records management" was sometimes used to refer only to the management of records which were no longer in everyday use but still needed to be kept – "semi-current" or "inactive" records, often stored in basements or offsite. More modern usage tends to refer to the entire "life cycle" of the documents.

Global pharmaceutical companies should have available modern methods of records management to ensure that these records are properly stored and easily retrieved if needed. Initial expenses incurred to introduce these new systems may be prohibitive at first but in the long run, these newly adopted measures will prove their cost efficiency. Some of the advantages of records management are: the ability to reduce floorspace occupied for storage, an increase in the speed wherein records can be retrieved, and the ability to maintain the records of an organization from the time they are created up to their eventual disposal.

Actelion acknowledges the need to keep a complete and accurate record of its activities, to meet the requirements of the company, the regulatory and legal authorities its auditors, and others affected by its actions and decisions. In the past months, a dedicated team at Actelion invested time and resources to analyze and make aware the current situation to the stakeholders in the company.

The first conclusions of the concept phase were that the practice of records management may involve: planning the information needs, creating, approving, and enforcing policies and practices regarding records, developing a records storage plan, which includes the short and long-term housing of physical records and digital information, identifying, classifying, and storing records, coordinating access to records internally and outside of the organization, balancing the requirements of business confidentiality, data privacy, and public access.

A great challenge, which Actelion will try to meet.

Actelion Pharmaceuticals Ltd was founded in 1997 by three researches, and now, only 13 years later, Actelion has become a global company with 2,300 employees in 28 affiliates around the world.

Needless to say that this growth is accompanied by an exponential growth of Actelion's records, electronic records and intellectual capital (policies, contracts, laboratory documents, minutes, emails...). This growth of records is estimated to double in size over the coming years.

Hence after ten years, from a start upcompany to a large, multinational pharmaceutical company the question how to manage all these records is becoming a challenging issue and consequently the idea of a records management project at Actelion was born.

However, to some managing records still represents one of the most boring business functions and is mostly just associated with archiving, not acknowledging the fact that records management is quite complex. There fore, the first tasks in our project were the following:

- to persuade the business users of the benefit of such a project,

- to match policies with the right tools and processes;

- to provide a suitable technical infrastructure,

- and to comply with business, regulatory and legal requirements.

What are records? They provide evidence of business activity and business decision, document what we do as Actelion employees, contain unique or irreplaceable information and require special protection, require legal, fiscal or tax purposes and can be in any format.

- Results from our research, which we want to make available to future generations of researchers

- Evidence of successful inventions, for which we may need to defend our rights to patent

    Contractual obligations with third parties

- Evidence of proper financial conduct (on behalf of auditors and tax authorities)
- Emails, if they contain valuable conversations within Actelion or with external parties

What is records management? All dictionaries give a clear definition but really for our business this means;

- manage retention schedules,
- store records in their appropriate classifications along with the prescribed metadata,
- search for records when required,
- destroy records according to prescribed schedules,
- put holds on records so they don't get destroyed while the company goes through an audit or investigation, and track the access of the record over its active and inactive life cycle

Does records management cross numerous disciplines?

– Categorization and indexing are two elements that are critical to the success of a records management program: sounds a little like knowledge management.

- That vital records preservation is one of the key steps in developing a disaster recovery plan: sounds like infrastructure management.
- That by ignoring records management policies employees and their companies can potentially end up facing criminal penalties: sounds like a legal profession.

Why is it so important to embark in a records management project?

Good records management: improves operational efficiency, supports knowledge management, contributes to corporate memory. Good records management is essential for sustainable growth.

What are the benefits of this record management program?

Benefits of the program will be both qualitative and quantifiable and include measurable improvements like:

- Company records can be retrieved fast and complete.
- Records are securely stored in compliance with laws and regulations.
- Records can be shared while access control is ensured.
- Gain transparency about which records we have.
- Paper archives can be moved to electronic archives.
- Every employee is aware of the value of records and how to treat them.

How should the records be kept?

- Records must be retrievable
- Protect records from unauthorized destruction
- Protect permanent records
- Provide access to records

Company records, such as laboratory notebooks, product information, financial information, and government filings, must be accurate and verifiable records of all activities and transactions. All data must be recorded according to Actelion's scientific, manufacturing, and Quality Assurance/Quality Control Standard Operating Procedures, and in accordance with all applicable laws and regulations.

The manner in which information is recorded reflects on the company's scientific and business integrity, and all employees are responsible for adhering to the highest standards of their profession.

With all the responses to the questions above an analysis report of the current situation was written and a prioritized list of the next steps towards mitigation of existing risks and closing or identifying gaps was created.

All interviews of business units show that some individual solutions have been found to meet the regulation needs, but in most cases it is a temporary solution.

The needs for a records management are visible and desirable. But what are the priorities? Which corner stone should be put first to have a strong and sustainable structure?

For Actelion, "records" are its most important asset: they are evidence of everything the company has invented or is about to invent. Records are the memory of the company, as personal memories in the heads of Actelion staff; and as paperbased, digital, or even physical information in our archives, on our systems and in special refrigerators.

However, judging from the diversity of "records" one might wonder if it makes any sense at all to talk about managing "records" on a company wide level. So let's talk about the expected benefits of records management:

- Gain transparency about what records we have.

- Knowing where to search for a particular type of record, without reliance on personal memories.

- Finding records faster, and find everything relevant to a problem.

- Be able to manage access security to sensitive or confidential records.

- Be able to transfer paperbased records to digital format.

- Assure reliable archiving of electron ic records.
- Be able to dispose of those documents, information, etc. we do not regard as "records".

In short: be more efficient by clearly distinguishing what we value and what not, and then manage that part we value.

In parallel a presentation of this project was made to the top management and the results of phase I were summarized in order to stimulate their interest and support.

During the last months and working closer with several departments in the first analysis phase of our project, we discovered that this global records management concept is difficult because we have so many different views and options. Should we focus on a global archive for Actelion, like a central archive with an archivist, or should we support the individual initiatives overseen by a comprehensive definition of records management?

Now we have to ask a last, but the most important question: What do we want to achieve? What is the best solution? The answers to these questions will have a big impact and will determine the next project phases.

Now that the scale of demand is known, phase II, planning of implementation, can start. phase III, the implementation, will be the last and most rewarding step, but obviously also the most challenging.

In phase II we foresee a project management structure, where we will define project scope, deliverables, budget, and a project plan. In any case this project must be sponsored and endorsed by top management. Subsequently the following steps are fore seen:

- Based on outcome of phase I define a RM strategic direction paper and obtain buyin by stakeholders,
- establish a records catalogue, in which all business critical records are known,

- define an IT platform for compliant storage/archiving of records,
- establish policies and guidelines for records management.

The decision was taken to establish a companywide records management function and records management strategy with the creation of the necessary policies, guidelines and SOPs for RM. It was also proposed to establish a catalogue of records (vital or not, retention period, access control, alteration, procedures for deletion) and to define the responsible persons within the or ganization (records managers, data base managers . . .) who are responsible for the oversight of record keeping practices.

All this keeping in mind that this project has to be carefully planned, launched and its progress monitored over its entire lifetime. This includes: initiatives, investments budget and running cost, getting full support of all business units and IT for the program.

That's why it is important to establish an experienced team, in records management and project management as well as excellent communication and consultation skills, of at least two or three core members to coordinate and conduct the project.

We realized that we are just at the beginning of a long journey. But let us move on!

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