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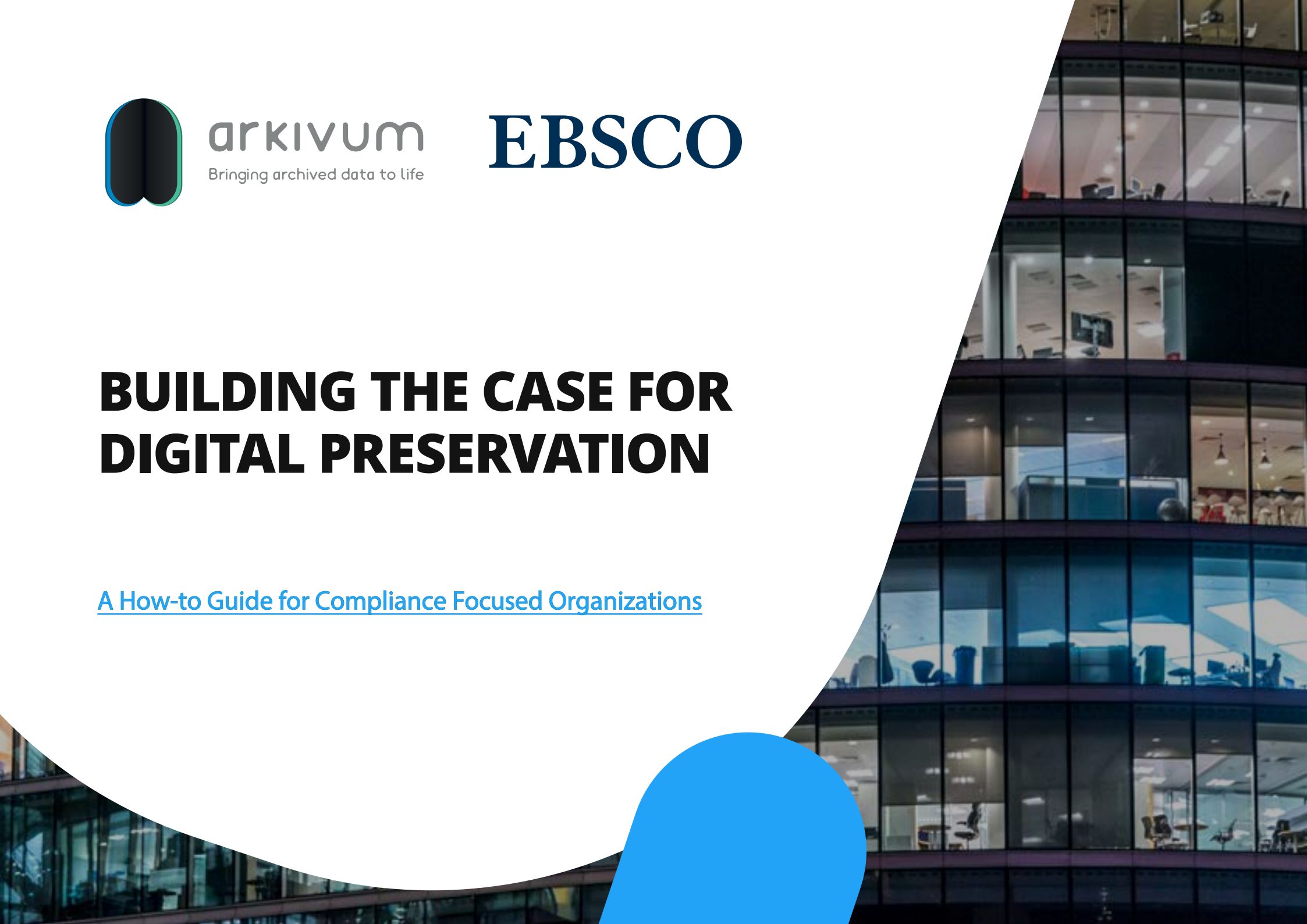
BUILDING THE CASE FOR DIGITAL PRESERVATION

A How-to Guide for Compliance Focused Organizations



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Are You Struggling to Communicate the Value of Data Archiving and Preservation?

Are you struggling to build the case for a digital preservation solution to support your long-term digital transformation strategy and plans?

Digital preservation is often only considered when it is already too late as an organization has not fully understood the need for and importance of a robust and thorough approach. With an ever growing plethora of data regulations to comply with and more born-digital data being created than ever before, it is imperative that organizations see the value in an effective digital preservation strategy.

An effective approach entails both the appropriate processes and tools are in place to ensure the effective safeguarding and preservation of your data. This requires investment.

Yet even the most seasoned professional can struggle to make the case for investing in such systems. Digital preservation and archiving solutions are very specialized tools, the 'nothing to something' nature of the proposition can be especially challenging.

As experts in this area, we understand that many IT and departmental managers will have little or no awareness of long-term data management. You will have to educate decision-makers as well as sell your vision to them.

This guide is designed to help you to sell that vision, from early preparation work – such as defining the scope and engaging stakeholders – through to the writing stage. It should help you articulate the value of digital archiving and preservation and put everything in place to drive change within your organization.

Why Digital Preservation Really Matters to Compliance-Driven Organizations

Regulatory compliance is a significant driver for data preservation, and can even overshadow that mainstay of business cases – cost savings. Your organization may not need to keep the data to perform its original function in the data process, but may well need to go back and reconstruct a process, prove that a drug has been fully tested, or demonstrate full data integrity and traceability in research.

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of organizations don't have a business case in place for digital preservation

Your business case will have to do more than simply underline the need for compliance; it will have to pinpoint those regulations relevant to the preservation of data in your organization.

When you're identifying appropriate regulations, consider these four categories of data compliance:

- **Providing evidence** – Consider ALCOA data integrity guidelines as a foundation for your case. In the pharmaceutical industry, to trace the process a drug undergoes in R&D and in licensing or litigation, for example, calls for attributal evidence of research and clinical trials. This will reassure regulators such as the MHRA that best practice is being followed. What most, if not all, regulators like to see is evidence that every effort is being made to put systems and processes in place to safeguard full compliance.
- **Securing research funding for discovery projects** – Non-compliance can, and frequently does, put future research funding in jeopardy. In recent years, research councils have enjoyed greater powers to veto future research plans where there is a failure to adhere to data preservation and archiving guidelines.
- **Cutting the cost of non-compliance** – Above all, organizations across a number of sectors recognize the return on investment of solutions that minimize the considerable costs of non-compliance in terms of litigation, loss of business and diminished reputation.
- **Reusing Data** – In early pre-clinical R+D being able to re-use data and being able to share data can help speed up research and discovery.

Complying with GDPR

Punitive penalties of €20million or 4% of global turnover make GDPR a critical area of compliance management.

Fully effective from 25 May 2018, the General Data Protection Regulation (GDPR) applies to organizations in every sector, and centers on the rights of European citizens to control usage of their personal data. Institutions will have a 'duty of care', requiring them to protect personal information from loss, alteration or unauthorized processing.

GDPR will regulate data on EU citizens wherever it is located in the world, and EU businesses will have to apply GDPR to all personal data. The regulation will prescribe the responsibilities of data owners very closely, making them more accountable for the activities of their data processors, even in the case of outsourced services.

Complying with Global Regulations such as MHRA GXP & EMA guidance

A highly influential regulator worldwide, MHRA (Medicines and Healthcare products Regulatory Agency) has set out its **guidance for data integrity** in pharmaceutical manufacturing.

The MHRA states that data governance, in either printed or electronic formats, needs to be integral to pharmaceutical quality systems. It sounds a pragmatic note, however, by stating that the data governance it prescribes needs to be balanced with other quality assurance demands. As such, manufacturers and analytical laboratories are not expected to implement a forensic approach to data checking on a routine basis, but they must design and operate a system that provides an acceptable state of control appropriate to the level of data integrity risk.

The MHRA has also issued good clinical practice (GCP) requirements that must be followed when designing, conducting, recording and reporting clinical trials that involve people.

Finally, the European Medicines Agency's (EMA) guidance on Trial Master Files (TMFs) came into effect in mid-2019. Now companies throughout the life science industry may need to store eTMF and clinical data for over 25 years and in line with the ALCOA+ principles. This poses a question for companies in the US which have no such law domestically as yet, but will likely want to maintain compliance in the EU and potentially invest in future-proofing their processes at the same time.

Complying with Research Councils

In academic institutions in the UK, Europe and America, funding bodies, research councils and governments now mandate that all research data be kept for at least ten years after the date it was last accessed. That can mean storing data that is only accessed every nine years for a period of 50 years, for example. So your organization needs robust systems in place to meet that requirement.

In its commitment to transparency and consistency across all research institutions, Research Councils UK (RCUK) is one of a number of funding bodies to issue guidance on data policy. This stipulates that data needs to be:

- As openly available as possible.
- Fully attributed.
- Managed in line with relevant standards and best practice.
- Discoverable and re-usable, supported by clear and effective meta-data.
- Released only with due consideration to legal, ethical and commercial constraints.

Subject-specific councils such as the Engineering and Physical Sciences Research Council (EPSRC) make further stipulations. The EPSRC has set down its **nine expectations of research data management**, assigning responsibilities and mandating the deployment of systems, tools and support services.

Cost Efficiencies Really Matter

Business cases that do not reference financials in some way are rare, and only in exceptional cases will they get approved. Fortunately, in the case of data preservation, operational efficiency gains are significant. Key examples include improved data access, minimization of duplicated work between staff members and departments, and cutting out the 'waiting time' that many currently experience without instant availability of information.

Any metrics you can source to quantify the cost of inaccuracy and duplication will support your case.

Office workers can waste up to two hours a day looking for misplaced paperwork, according to **The Global Trade Association for Information Management Companies** and managers spend an average of four weeks searching or waiting for misfiled, mislabeled, untracked or 'lost' information.

This quantified picture can be supplemented with powerful arguments, such as the value of getting new products and services on to the market thanks to the research efficiencies that a centralized data repository provides.

The Cost and the Risks of Doing Nothing

A benefit-driven business case, drawing on the checklists in section two, is the only way to succeed. But today's sponsors, like most executives, can be highly sensitive to risk, and your business case should address this.

By outlining a 'doing nothing' scenario, which should include 'doing the minimum', you are giving stakeholders a baseline from which they can assess the solution you're proposing and should highlight the risks of the incumbent arrangement. A makeshift internal storage solution will fail to deliver the robust life-cycle management solution your organization needs.

Opportunity Cost

The opportunity cost of a paper-based or sub-optimal archiving system forms an important part of the case for a data archiving and preservation solution. An obvious and direct example of opportunity cost is the revenue your organization could be missing out on by failing to monetize its archived resources.

Non-Compliance Risks

Non-compliance in many sectors is subject to increasing fines from powerful regulators. This is particularly true in highly-regulated markets such as pharmaceuticals, but even organizations like museums may face punishing fines with GDPR and other data regulations.

Without a robust data preservation solution, your organization is vulnerable to the complexity and shifts in data regulation, and to the risk of non-compliance, which can ultimately wreak havoc on reputation.

Data Loss

Organizations that fail to put in place a data preservation solution run the very real risk of data loss. Fire, theft or mere accidents – scenarios such as data stored in a bag of hard drives in the office cupboard – can and do happen to organizations such as yours. If not that, then the ever-present threat of a cyber attack is something every organization needs to mitigate. **Almost half of UK companies** were hit by a cyber attack or data breach over a recent 12 month period. One UK university managed to recover the 60 archival collections it lost in one such incident, but at considerable cost to the institution. There was some corrupted data, and all meta-data was irretrievably lost. Often the cost of recreating data is significant. Even if the data is recreated data integrity may be undermined.

Financial Loss

The user experience of leading websites such as Amazon has elevated the expectations we all have as customers of online services. Real-time availability of data and information on high-performing applications is not negotiable without putting your user base and reputation on the line. Research organizations also face the risk of funding losses without putting suitable systems in place or demonstrating compliance with the regulations.

Preparing Your Business Case

This section will take you through the key stages and areas you need to consider as you prepare your business case. Before you start, are there any previous digital preservation projects you need to be aware of? If they have been unsuccessful, then make sure you factor in any lessons learned into your own business case and project plans. And look for any infrastructure or internal expertise that you can make use of.

Scope

By the time you start writing your data preservation and archiving business case, your high-level objectives – the goals you want to meet and the problems you need to solve – should be clear. The **Digital Preservation Coalition (DPC)** recommends setting out the scope very early in the business case, relating it to your problems and goals in a clear way. Failure to define your scope will mean problems later on, especially when working out costs. That said, as you engage stakeholders and maybe potential suppliers, for example, you might revisit and refine your scope. Try to keep 'scope creep' to a minimum though.

In setting the boundaries of your business case, the DPC suggests drafting 'in-scope' and 'out-of-scope' lists. These can even be included in the business case itself, to provide clarity, possibly in an abbreviated form. Significant 'out of scope' items can be supported with explanatory notes on how you propose to address them elsewhere.

By scope, we are not only referring to objectives; we should also specify the time period involved. Is it a pilot project, for example, or a longer-term program encapsulating all your research and collected data?

Stakeholder Engagement

With any business case, identifying the key decision-maker and budget-holder is crucial. You will need to compose your central arguments and shape your proposal around those individual people, their capabilities and their responsibilities. So if the person who will ultimately approve your business case is a finance manager, then your proposal should be highly precise in the costs it outlines and may have to explain technical details that you yourself take for granted. If the business case approver is a digital champion, then your proposal can be more visionary at a technological level. The key stakeholder you identify will have a direct bearing on the form that your business case document eventually takes, in terms of format, structure, tone and level of detail.

Stakeholder engagement isn't just something you do in the background to help your business case succeed. It should also be a section in your business case document, outlining the key areas of need and how your proposal meets them.

Identifying Stakeholders

Identifying the primary stakeholders will require an understanding of your organization and its structure. The first question you should ask yourself is – why is it important to safeguard data? And then you should consider to whom it matters most.

If you haven't already got one in place, then identify a champion on the senior management team, and discuss your plans with them informally, as the DPC advises. The constructive feedback you receive will help shape your case. It's a good idea to support this engagement by scanning the organization's strategy and any relevant operational plans and policies.

Who else in the organization needs to be involved?

- Senior Management Team – They will need reassurance that resourcing is secure and that the project will deliver cost savings and time efficiencies
- Operational Staff – They will be looking for a solution that is fit for purpose and easy to use, so they can get optimal value from the data
- IT – They will want responsibility for valuable assets to be given to an expert provider they can trust and work with easily and effectively
- Users – They will value instant access to resources whenever they need them
- Partners – As well as access, they will want a degree of control over data, and reassurance that any risks are identified and managed.

A stakeholder analysis exercise will help you to identify who else to involve, and you will need to address their expectations of the project and its outcomes in your business case and priorities.

Engaging Primary Stakeholders

You should engage directly with all the stakeholders you identify, asking them:

- Why they care about data preservation and archiving.
- What the project will cost them in terms of time, cost and resourcing.
- How the solution will impact their area of responsibility.

This can be presented in a clear, tabular form in your business case document.
A surprising number of business cases fail to consider every stakeholder from every angle.

All your engagement activities should be about justifying your plans and then refining them as you uncover their perspective and experiences. You should be prepared to engage your stakeholders in a variety of ways. We've seen successful stakeholder engagement in the form of workshops and round tables, whatever suits your stakeholders best. Any commitments and endorsements from valued stakeholders at this stage should be referenced explicitly in your business case.

It may not run completely smoothly; there may be conflict. The resourcing involved in the project may be unacceptable to some managers, for example, or there may be a feeling that the funding could be better spent elsewhere. It is better to discover that at this stage though, and tailor your plans to anticipate any opposition – with a GANTT chart that pre-empts resourcing concerns, for example – than to end up with a failed business case that lost its credibility by ignoring potential obstacles.

Getting the Timing Right

You could write a compelling business case, and your stakeholders may well buy into the solution and agree with your arguments. But what if they turn around and ask – why now?

Getting the timing right for data archiving and preservation can be trickier than it seems. The status quo can be strangely comforting, even for some forward-thinking stakeholders. Here are some questions that will help you present your business case at the right time for your organization:

The Compelling Event

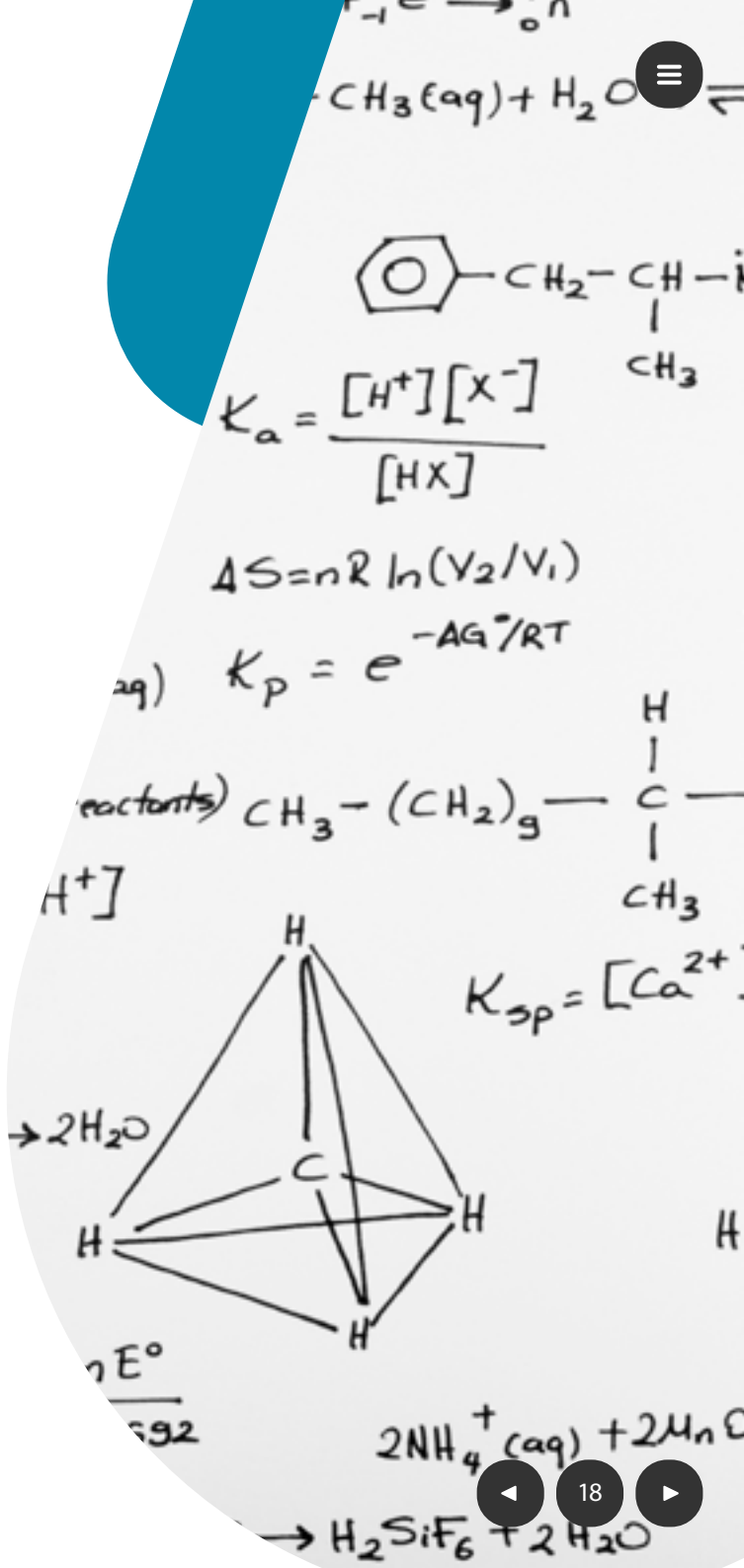
Behind a successful digital preservation business case there is often a compelling event.

What a compelling event is will depend on your organization, but successful instances include failing software solutions, an office relocation or refurbishment, and a real-life horror story that has caught the attention of stakeholders, involving the loss of precious archive assets due to a disaster, a cyber attack or, most commonly, human error.

Other examples might include:

- A change in regulations such 2019's EMA guidelines.
- End of life repository, content management platform or infrastructure platform
- A new funding round or opportunity.
- Evidence of regulatory non-compliance that may incur a severe penalty.
- A clear risk of information loss, such as data stored in an office cupboard, or a paper archive in a location that is vulnerable to flooding.
- Issue accessing specific records due to old formats or data loss due to application data lock-in.

You may not always have any of these, but if you can engineer a realistic compelling event to drive your business case, then that will create the natural sense of urgency to do something rather than nothing.



Organizational Planning and Budget Cycles

You should time the publication or presentation of your business case in line with organizational planning and budget cycles. You can then prepare your stakeholders for submission. This may involve refining the format to adhere to internal planning and budgetary standards.

Is Your Organization Waiting for the Perfect Solution?

In areas such as digital preservation, where full solutions are in the early adopter phase, waiting for full technological maturation can seem to make sense. But does it really?

Your organization will be waiting a long, long time for the perfect solution to appear – and Section 3 highlights the risks involved in 'making do' with your current arrangements.

Today's software solutions are upgraded on a regular and incremental basis, meaning that you can start safeguarding your archival assets right now, and should 'perfection' come along, you are perfectly positioned to realize the benefits straight away.

What If It Really Isn't the Right Time?

In certain circumstances, delaying the submission of your business case may be the right approach, for now at least. You may not be ideally positioned in the planning and budget cycle, for example, or a key stakeholder may have left the organization.

If this is the case, then you need to maintain momentum in a constructive way, to avoid jeopardizing your migration to digital preservation. DPC advises using the intervening period to build momentum, by engaging with stakeholders and strengthening your case with the latest evidence. Support this with a robust communication plan.

Another helpful approach is to keep a record of the measures you're having to take to maintain the archive, without a solution in place. If you don't have metrics for the time taken to follow manual processes, then this is a great time to gather them. So you can strengthen your business case as well as keep your stakeholders interest. But make sure you've set a clear date on when to move forward, or you really will lose momentum.

Taking a Phased Approach to Digital Preservation

If you're preparing a business case for data preservation, then it's likely that you have a vision that is transformational. However realities can soon bite in terms of budgeting and resourcing, as we've already discussed. It's also important not to overwhelm your stakeholders. Data preservation and archiving projects can become unwieldy, and what we call 'action paralysis' can set in, with too many people or departments involved in an unfamiliar initiative. The risk of ending up back in 'do nothing' territory is all too real at this point.

In our experience, a phased approach is the best way to avoid this problem, safeguarding data and widening access in a controlled but effective way. This makes the business case look much more feasible and manageable to the stakeholder. If that means starting with a very small area of your overall archive, then you have at least made a start in protecting your data, complying with regulations and widening access.

By presenting digital preservation as a phased programme, you are giving stakeholders reassurance that review points are in place, that the approach can be refined as experience accumulates. At the same time you're managing the risk of doing nothing by working on the solution actively.

How to Phase Your Data Preservation Project

What that looks like will depend on the specifics of your organization. But however you decide to define your phases, you should start with either a champion department, or an area where the pain is particularly acute – where a data breach has already happened, for example. In other words, start by working with the people who already 'get it', whether that's a team or a particular collection of data. And then phase two might prioritize high risk data.

Another approach that is gaining traction is to take a feature-led approach. So phase one in this project might involve securing the data, making sure it's checked and encrypted, and replicating it across multiple locations. Then in phase two you can turn your attention to file format preservation, for example. And phase three can be a fuller roll-out.

Early Engagement with Potential Suppliers

Your potential suppliers have already accumulated a great deal of experience of data preservation projects – particularly valuable with early adopter solutions. They may be able to point you to similar organizations that have live data preservation solutions in place, and even arrange site visits for you.

They can also provide information for your business case. Ask them for resources such as feature sheets, videos and even product demonstrations. And start talking to us at an early stage. We can even facilitate a half-day brainstorming workshop with your stakeholders. Don't worry about not having budget secured – this is a new area so it's less likely that you'll have the funding in place at this stage.

Formal Tenders or Requests for Proposals (RFPs)

If you need to go through a formal tender process, be careful about the weighting you give to the cost of the solution compared with the features, benefits and outcomes it delivers. What matters most are your problems and goals. Make sure your tender is not designed to get the cheapest supplier, but instead opens the way for a fully fit-for-purpose solution.

Framework agreements can also simplify the PQQ (Pre-Qualification Questionnaire) stage of a formal tender. They provide organizations in sectors such as local government, higher education and certain industries with a list of accredited suppliers. This can provide internal reassurance, and make it easier for you to work productively with your procurement department. Framework agreements remove a lot of the risk, and bureaucracy, involved in procuring solutions from a new supplier.

In the healthcare sector, cost saving is an important factor in system specification, and the Arkivum solution functionality and ease of use has greatly helped us achieve our goals in this area.

Nick Housby, Head of Business and Operations, Oxford Molecular Diagnostics Centre

What Will Your Business Case Look Like?

Once you're ready to produce your business case, you need to decide on the best format for the specifics of your organization and project. The likelihood is that you will have to write a formal proposal of some type, even if you have engaged extensively with stakeholders, in ways we've suggested, up to this point.

The journey your business case takes once you've drafted it has a bearing on what it should look like. Is it a document that you will have to submit to a board or a committee? Or are you applying to an external funder?

Some formats will be specific to a project management methodology of framework – such as the PID (Project Initiation Document). Others, such as the RFP (Request for Proposal) are required for a formal tender process. Even if the format is prescribed, though, it's worth finding out how flexible that format is – to give yourself every chance of optimizing your argument within those constraints.

To structure your proposal, follow this checklist to make sure you have included sections that your stakeholders expect to see:

- Executive summary – Including a high-level summary of recommendations.
- Introduction – Background information, objectives and problem statement.
- Business drivers and anticipated benefits – Targeting the appropriate stakeholder type.
- Fully quantified cost-benefit analysis.
- Project overview.
- Solution description, with options if applicable.
- Timeline.
- Budget.
- Success criteria.
- Recommendations.

Data Archival and Preservation – The Arkivum Solution

Our data archival and preservation solutions deliver benefits in these areas:

- **Preservation -** Ensure data is usable and accessible for the long-term.
- **Safeguarding** – Highest standards of data protection.
- **Usability** – Accessible, usable and exploitable data.
- **Compliance** – Seamless compliance with sector-specific regulations.
- **Data sovereignty** – Total control of data storage location at all times.
- **End-to-end managed service** – Complete data life-cycle management.
- **Integration** – Integrated to ecosystem of connected services.

Arkivum TRUST

Arkivum TRUST is an end-to-end, secure digital preservation archival solution built to address the unique challenges of the life sciences, pharmaceutical and health markets. Arkivum TRUST is a modular solution that scales from entry level to an enterprise solution, helping you predict and manage IT costs at every stage of your digital preservation program.

Arkivum TRUST helps life sciences organizations meet core MHRA and FDA GxP guidelines and regulations for data integrity and long-term digital management.

Arkivum TRUST delivers the following benefits:

- Minimized risk of non-compliance – With automated data safeguarding and preservation of digital assets.
- Reduced management overheads – By managing regulated digital records with a simple user interface for staff and inspectors.
- Future-proofing – Protecting your organization against technological obsolescence, with long-term retention and the cost of recovery for files through automated file format preservation.
- IT cost savings – By managing all data archiving irrespective of age, format, location, regulation and file type.
- Ease of integration – Helping you work with data partners on streamlined digitization processes and validation management.
- Risk management – With a comprehensive, multi-system integration into one place.

Arkivum TRUST is designed to ensure your digital files remain accessible and usable for the very long term, and comes with a 100% data integrity guarantee. The solution can be extended through a number of supported integrations to provide additional features and benefits such as public or private access, search and discovery.

About Arkivum

Arkivum is the trusted software and service provider for managing your data securely for the long-term. We deliver solutions that help organizations to:

- Safeguard and preserve their most valuable digital content to the highest level.
- Comply with the intense regulations governing digital records management.
- Handle growing data volumes while making archived data usable and accessible.

Arkivum provides a safe, secure, compliant and accessible digital archiving solution, for both structured and unstructured data, with storage in the most appropriate location, and integrated with other business systems. Arkivum solutions bring archived data to life by opening up the vast, often untapped value of archived repositories. We offer a unique 100% data integrity guarantee and built-in escrow service.

Since 2012 Arkivum has been serving more than 120 organizations worldwide across regulated industries and has ISO 27001 certification. Our clients value our end-to-end managed service and simple solutions that meet complex challenges.

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