WHITEPAPER

PDF association

PDF/A Competence Center

PDF/A is a long term archiving format which provides the health care sector with new ways to store information and archive documents consistently and efficiently.

PDF/A in Healthcare

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About this white paper

The healthcare sector's retention period for medical documents can be 30 years or more. In addition to classical documents such as doctor's notes, statements and lab reports, other items such as X-ray or tomographic images often need to be kept for a long period of time. For reasons of legal security, digital signatures are important for medical reports, not least because they provide a clear and unalterable record of when they were produced (timestamping).

PDF/A provides decisive advantages when digitising patients' files. These include the ability to scan documents in colour, as well as full text search capabilities after OCR, while keeping file sizes relatively small. As with PDF files, any signatures needed can be included in the modern PDF/A format as embedded signatures.

Another point of emphasis for the healthcare sector is combining structured information with an appealing visible presentation in a single document. While the increasing amount of data being exchanged directly between health sector entities requires the use of standardized data structures like HL7 or CDA, which are based on XML, it is important for people to be able to read and edit these documents. Integrity and authenticity are also increasing in importance. The PDF/A format is uniquely suited to meet these needs and the requirements of both information sources and information recipients.

The PDF Association is an international organization promoting awareness and adoption of open standards in digital document applications using PDF technology. The association facilitates networking and communication, and the sharing of expertise and experience with interested parties worldwide. The current membership includes over 100 enterprises and numerous individual subject-matter experts from more than 20 countries. The PDF/A Competence Center is the first and currently the largest division of the PDF Association. The Special Interest Group 'PDF/A in Health Care' is also part of the PDF Association. Its objective is to provide meaningful, practical information that ties in with the requirements of the health care sector. The Special Interest Group was founded by seven members of the PDF Association while attending the 2012 Schliersee Conference: DMI, eHealthOpen, intarsys, LuraTech, OPTIMAL SYSTEMS, secrypt and the SRZ. BancTec will also participate in the SIG as a non-member.

The purpose of this white paper is to provide general information about the PDF/A standard, as well as possible applications of PDF/A. Readers will also be able to learn about real-life usage examples. The white paper also includes a brief presentation of the members' products and solutions.

The PDF Association would be happy to answer any questions you might have about the PDF standard.

Berlin, April 2012

Dr. Bernd Wild, Board member

Thomas Zellmann, Managing Director

1. The PDF/A Standard

1.1. History

On 28 September 2005, the International Organization for Standardization (ISO) defined a standard for a document file format for long term archiving of electronic documents:

ISO-19005-1 - Document management - Electronic document file format for long-term preservation - Part 1: Use of PDF 1.4 (PDF/A-1).

Work on the standard began in May 2002 in the USA. The objective was to create a document format on the basis of an existing format and define rules for how it could be used for long term archiving, rather than building an entirely new format from the ground up, as this would have made it extremely difficult for the new format to gain worldwide acceptance. The format chosen was the PDF Reference Version 1.4. The initiative was launched by AIIM (Association for Information and Image Management), the NPES (National Printing Equipment Association) and the Administrative Office of the U.S. Courts. The kick-off meeting was held in October 2002 and included well-known PDF suppliers, including Adobe Systems, Library of Congress, Surety Inc., Quality Associates Inc., Appligent, Merck, EMC, PDF Sages, and the NARA (National Archives & Records Administration). Subsequent attendees included Xerox, Honeywell, EDS, and Glaxo Smith Kline.

The initiative prepared a first draft and submitted their project to the ISO to be registered as an International Standard. The ISO assigned the project to a Technical Committee (TC 171 – Document Management Applications). TC 171 is comprised of 15 participating countries (who each have one vote) and 21 observer countries. After numerous reviews and amendments, the standard was approved as ISO 19005-1, more commonly known as PDF/A-1, in September 2005.

However, work on the standard was not yet done. Based on the experience gained from introducing PDF/A-1 to market, which the PDF Association's PDF/A Competence Center made a significant contribution to, additional requirements related to the long term archiving of electronic documents were analysed, leading to the publication of Part 2 of the Standard, ISO19005-2, or PDF/A-2 in autumn 2011. The third part of the Standard, PDF/A-3, is expected at the end of 2012, and will expand PDF/A's capabilities as a long term electronic format for a wide range of information.

1.2. PDF/A-1

PDF was originally a proprietary format controlled by Adobe Inc., and is now published by the ISO as ISO 32000. It is a page-oriented, platform-independent document format. In addition to providing resolution and device-independent representations of documents, the PDF format now has numerous interactive and dynamic options, such as forms, using JavaScript or embedding external formats. However, these features are not suitable for a document format intended for long term archiving which also needs to present information solely on the basis of the specification. Instead, the format has to be 100% self-contained, with every file containing all of the resources needed to accurately display the original document. With these requirements in mind, the PDF/A-1 Standard describes the elements in the PDF Reference 1.4 which can be included in a PDF/A-1 document, which cannot, and which elements are mandatory. The end result is a genuine PDF, which also meets the requirements of the PDF/A-1 Standard.

In order for a PDF to qualify as a PDF/A-1, the main requirements are that it:

- can embed every type of font in use (TrueType, Type 1, Type 3)
- uses the OutputIntent property to identify colour spaces
- does not include encryption or access rights
- uses XMP-based metadata
- has no interactive content, such as JavaScript, 3D or Multimedia
- does not embed external formats (e.g. office documents, videos, etc.)
- restricts images to certain formats, such as JPG, TIFF, JBIG or JBIG2
- does not include transparent objects

All other PDF 1.4 elements, such as embedded digital signatures, are permitted. Another difference between the standards relates to

conformance levels. There are two PDF/A-1 levels: PDF/A-1a and PDF/A-1b. While level 1b documents are not required to contain any information about the structure of their content, this is a requirement for level 1a documents. This information relates to the semantic structure of a document, such as "Heading", "Chapter", "Footer", etc., which are functions in a similar way to the tags used in HTML documents to identify page elements. These structures make it as easy as possible to access the document, as they can be used to navigate within the document and provide multimedia output, such as text to speech. However, producing a PDF/A-1a compliant document requires some preliminary work in the source document, which makes it impractical to convert a PDF to PDF/A-1a later. The vast majority of PDF/A-1 documents in existence comply with conformance level 1b, which means that one of the main objectives of the standard, creating a form of "electronic paper", can be achieved. PDF/A-1b has proven itself to be particularly suitable for digitising paper documents (scanning, OCR applications).

1.3. PDF/A-2

Several of the limitations in PDF/A-1 were due to version 1.4 of the underlying PDF

specification. These includ the permitted image formats and embeddable font formats. The PDF/A-2 standard was published in autumn 2011 and introduced the following additional features:

- use of the JPEG2000 image format
- embedded OpenType Fonts
- support for object transparency (e.g. "soft" shadows)
- support for embedding other PDF/A-1 or PDF/A-2 compliant files (known as
- file collections)

While the ability to save images in JPEG2000 format was a welcome new addition for users using the format to "digitalise paper", the ability to embed other (A-1 and A-2 compliant) documents in a PDF/A-

2 file opens up a range of new applications. While individual documents were previously combined in a type of portfolio by an existing archiving or DMS system, this can now be done on the document level directly without having to rely on document management systems. This opens up areas of application like digitised patient files, insurance files or archiving emails, which can be converted to PDF/A-1 or PDF/A-2 along with their attachments.

PDF/A-2 also has multiple conformance levels (a, b and u), which are largely similar to the conformance levels used for PDF/A-1. An overview of the differences between PDF/A-1 and PDF/A-2 and their conformance levels is included below.

	PDF/A-1		PDF/A-2		
	PDF/A-1a	PDF/A-1b	PDF/A-2a	PDF/A-2u	PDF/A-2b
Reproduction	Visual and semantic structure	Visual structure	Visual and semantic structure	Visual structure plus all text in Unicode	Visual structure
PDF version	1.4		ISO 32000 (PDF 1.7)		
PDF/A identifier	PDF/A level and conformance level must be specified				
Metadata	Document metadata must be XMP-compliant		Document and object metadata must be XMP-compliant		
Logical structure	Tagging, alternative image descriptions, language used	–	Tagging, alternative image descriptions, language used	–	–
Encryption	forbidden				
Colours	Identification of all colours Device-dependent colour areas identified using OutputIntent				
Transparency	forbidden		allowed		

	PDF/A-1		PDF/A-2		
	PDF/A-1a	PDF/A-1b	PDF/A-2a	PDF/A-2u	PDF/A-2b
Compression method	LZW not permitted				
	JPEG2000 not permitted		JPEG2000 permitted		
Fonts	All fonts (and subsets) must be embedded Unique font codes must be used				
	Every letter must be reproducible using Unicode	–	Every letter must be reproducible using Unicode		–
Annotations	Audio and video comments are not permitted. Other text or markup annotations defined in PDF 1.4 are permitted.		Audio and video comments are not permitted. Other text or markup annotations defined in ISO32000 are permitted (e.g. watermark, collections)		
Referenced content	Referenced (i.e. non-embedded) images or page elements are not permitted				
Alternative images	Alternative images (e.g. lower resolution versions) are not permitted				

	PDF/A-1		PDF/A-2		
	PDF/A-1a	PDF/A-1b	PDF/A-2a	PDF/A-2u	PDF/A-2b
Scripting	JavaScript is not permitted				
Actions	Actions to start a movie or sound recording or for Email sending of forms or for resetting of forms are not permitted				
Forms	Permitted with restrictions (i.e. no JavaScript, no impermissible actions)				
Electronic signature	Embedded electronic signatures are permitted if the graphical representation is compliant with the PDF/A specification and is compliant with PDF 1.4		Embedded electronic signatures are permitted if the graphical representation is compliant with the PDF/A specification and compliant with ISO32000		
Embedded files	Not permitted		Permitted if the embedded files are compliant with PDF/A-1 or PDF/A-2		
OpenType fonts	Not permitted; conversion to Type-1 or TrueType necessary		OpenType fonts compliant with ISO/IEC 14496-22 are permitted		

1.4. PDF/A-3

In practice, one frequent request – in addition to preparing a source document as a PDF/A in an unalterable and visually accurate format - is the ability to also archive the source file or source format which the PDF/A document was created from. This is not so much about the ability to archive any file format for the long term (which is impossible due to the lack of standards) as it is about the ability to process the embedded source data. The difference between the PDF/A-3 standard, expected towards the end of 2012, and the A-2 standard revolves around precisely this issue: embedding any file with a MIME type. This opens up a wide range of options: electronic invoices can be created in PDF/A-3 format and contain an XML file to make the invoice data machine-readable. Doctors can draw up letters which take their visual appearance from the PDF/A-3 document while their structural data is embedded as a CDA-XML document. While there is no guarantee that it will be possible to reproduce the embedded files and data in the future, PDF/A-3 documents provide a stable and static representation suitable for long term archiving.

2. PDF/A in the Health Care sector

There are two issues which make using a document format for long term archiving like PDF/A particularly interesting for the health care sector:

- the retention period for medical documents under statutory and radiology law, which can be up to 30 years after the end of clinical or radiological treatment, and
- the wide variety of formats used for electronic documents in the health care sector, along with the applications and tools required to use them.

In addition to simply complying with minimum statutory retention periods, health care professionals are increasingly interested in being able to search through and evaluate historical medical files. In order to evaluate the long-term effect of medication or treatment methods, data needs to be in an accessible format which remains stable and specified for not just years, but decades.

The clinics, practices, laboratories, care institutions, preventative health care providers and service providers in the health care sector produce a prodigious amount of documentation, which is constantly growing in tandem with the technological and medical advances being made in treatment methods and processes. Up to now, most information was recorded on paper, with handwritten patient and treatment documents being exchanged by letter or courier, and paper being used by a wide range of specialists as the medium of choice for documenting results. Now, however, the pendulum is swinging towards purely electronic documentation. The use of multimedia content, like images, video recordings, sonograms, etc. is constantly on the rise. What is needed is a uniform, standardised format for all this documentation that can be evaluated while retaining its long term stability regardless of the application and supplier.

The PDF Association strongly recommends using PDF/A as a format for archiving electronic documents. While the first part of the standard, PDF/A-1, met the basic standards for archiving digital documents, only the new PDF/A-2 and future PDF/A-3 provide support for embedding binary content and machine-readable data. The table below shows the extent to which PDF/A is used or can be used for different applications in the health care sector.

currently	Producer/generated	Standard	Notes
Doctor's letters	HIS, Word etc.	PDF/A-1a	
Patient consent forms	PDF forms	PDF/A-1b	
Medical equipment inspection	HTML, PDF	PDF/A-1b	
Patient files	Digitizing paper	PDF/A-1b	No OCR, JPEG compression, no portfolios

future	Producer/generated	Standard	Remarks
Patient files	Digitizing paper	PDF/A-2	JPEG2000 compression, portfolios

future	Producer/generated	Standard	Remarks
Doctor's letters	HIS, Word etc.	PDF/A-3	Embedding XML net data (CDA doctor's letter)
Lab documents	Specialised systems	PDF/A-3	Embedding XML net data (lab data)

Existing paper archives and paper documents can be converted to PDF/A in the traditional fashion. PDF/A-1b documents are usually completely adequate for this purpose, and also offer the advantages of efficient JPG or JPG-based image compression methods, the option of overlaying text recognised using OCR, and the options to house metadata and signatures in a standardized fashion in a single compact file.

In contrast, electronic documents like doctors' letters, reports, etc., which are frequently created using software like HIS, PVS or Microsoft Office, can also be converted to the PDF/A-1a format, which is a richer format in an IT sense. In order to do this, the program used to create the document must provide the necessary structural information tags when the PDF/A is created. It is practically impossible to add this kind of information later.

The only significant change related to digitising paper documents that came about with the introduction of PDF/A-2 and conformance levels a, b and u was the option of using the JPEG2000 image format. This format reduces the size of the image without sacrificing quality. It also makes lossless compression of colour images possible, which is frequently required for radiological images.

There is a great deal of potential in file collections, which have been possible since A-2. The ability to combine multiple PDF/A documents into one "container PDF" makes it possible to create collections of documents which appear from the outside to be a single file. This makes it easy to create portfolios in a standardized way. With PDF/A-1, you needed to use an external DMS or archive system to combine related documents. PDF/A-2 allows you to do this directly from the document itself. PDF/A-2 is the ideal target format for both digitising paper files (like patients' files) and archiving procedures (hospital treatment) or emails together with their attachments.

The upcoming PDF/A-3 Standard will remove the limitation that only PDF/A-1 and PDF/A-2 compliant documents can be embedded in a PDF/A-2 document. This will make it possible to embed almost any external format into a PDF/A-3 document in a standardized way. Of course, the long-term stability of the format only applies to the PDF/A-3 part of the file, not the embedded external format. Nevertheless, this will allow the health sector to use archived PDF/A documents which not only contain textual and image-based descriptions of tests (treatment report, findings), but also a

video or a sonogram. Multi-format documents are another possible application. These contain information for human consumption in the traditional PDF/A part of the document, while the machine readable structured information is embedded in the form of an XML document. Because it is stored in a standardised location, this „payload" data can be extracted and processed without having to derive the information from the visual part of the document. This will remove the need for a lot of the OCR work done today. This dual information storage method has already proven its worth in electronic invoices and electronic documents in workflow systems.

The PDF/A-1, PDF/A-2 and upcoming PDF/A-3 standards were all created to meet the ever-changing requirements of the market and users in a wide range of sectors. The variety of document types and file formats used in the medical sector presents a significant challenge to the prospect of using a standardised document format. However, the PDF Association believes that there is now nothing standing in the way of the backwards-compatible ISO19005 Standards being used by the majority of the health care sector. It is now possible to use PDF/A as a standardised format for electronically archived documents.

3. Examples of use

3.1. PDF/A at the medical services centre of Greifswald University Medical Centre

Greifswald University Medical Centre traces its roots back to the 17th of October, 1456, when the university and its faculty of medicine were founded. Nowadays, Greifswald University Medical Centre provides a wide range of services and encompasses 21 clinics/polyclinics, 19 institutions and a number of government organizations. These facilities are currently spread across the city, but will be centralised in a single location by 2014. This restructuring will allow Greifswald University Medical Centre to increase its efficiency and level of innovation and become the most modern medical institution in Germany.

Greifswald University Medical Centre runs a number of medical services centres. They provide treatment in a variety of areas, including psychiatric and neurological care.

The medical services centres have decided to join the university hospital in moving from paper-based patient records to electronic, audit-proof archives. Due to the university hospital's positive experience of using the service provider DMI to help archive its patient records, the partnership was extended to the medical services centre in 2011.

The decision was made to archive the records in PDF/A format. As part of the process, the one-stop archiving services provider DMI embeds a signature and a timestamp in the PDF/A. This turns the medical services centre's patient records into reproducible, signed and self-contained archived material.

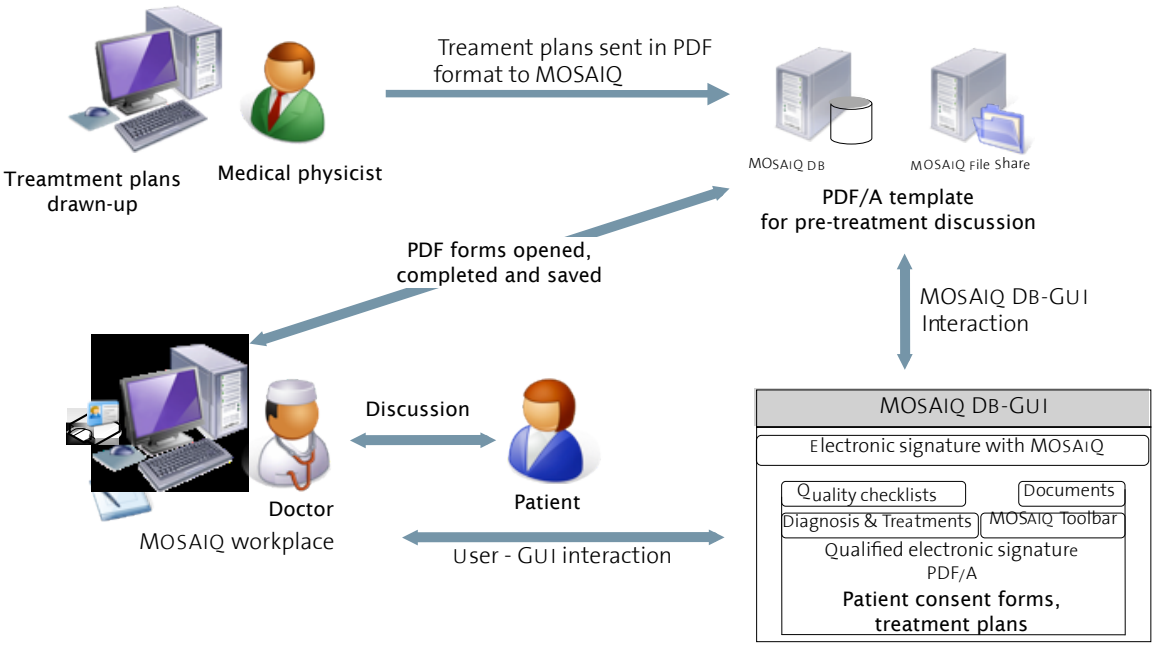
Dr. Frank Adler, who heads up the project in Greifswald, had this to say about the benefits of this solution: „DMI's archiving services and the PDF/A file format have given us the space and opportunities we need to make our processes more efficient. Our paper archive had grown so big that we were about to relocate it for the second time. Now that we've switched to electronic archiving with DMI, we won't have any more space issues. PDF/A is a future-oriented archiving format which provides a self-contained record of all the information we need. Better yet, we will still be able to open them with everyday software 30 years down the road."

3.2. PDF/A + signature = a successful combination

The Radiation Oncology Centre in Singen is a perfect example of a paper-free medical centre. With 1,500 patients and approximately 45,000 sessions per year, the centre relies on IT to optimise its workflows and keep waiting periods to a minimum. It uses an all-encompassing business process management solution to manage processes related to scheduling, radiation treatment record-keeping and legally compliant archiving. Patients benefit from short waiting times and appointments, which last just 20 minutes on average.

When the Radiation Oncology Centre in Singen was renovated in 2007, they wanted to move away from having a paper archive while still complying with the statutory 30 year minimum retention period for treatment records. All of its patient records are managed and archived electronically. The Oncology Centre relies on a solution provided by Karlsruhe-based PDF and signature specialists intarsys to prove that its documents are genuine and to make sure that its records comply with legislation. "We quickly realised that we needed to

take a close look at using electronic signatures. We also needed to implement clean electronic workflows, so that we were protected by the law. intarsys helped a lot with their expertise in this area," said Michael Obenland, a medical physician at the Radiation Oncology Centre. The centre uses preconfigured templates for their patient consent forms, which are displayed in PDF format using the Sign Live! application. Consultants use a special pen and convenient Wacom Tablet PCs to fill them out and save them. Using the application allows them to fill in boxes and add hand-written notes, drawings or markings. The form has obligatory and optional fields, and has built-in systems to check that the content of the form is valid. The consent section is an integral component of the forms. Patients can indicate that they consent to treatment by signing on the screen. The doctor then uses a qualified electronic signature to sign off on the entire procedure using their personal signature card. Both signatures are embedded in the PDF. To make it suitable for long term archiving, Sign Live! converts the form to PDF/A-1 just before it is signed. This removes all of the elements that do not comply with the PDF/A-1 standard from the form. Applying the signature completes the appointment and provides a complete record of it (see Illustration).



Patients can have a paper copy to take home if they wish. The digital PDF/A document is sent to the patient's file in the centre's electronic archive. "On average, there's between five and seven documents to manage electronically for each patient. That includes dosage regimens, which we create internally and sign electronically for the sake of transparency," explained Obenland.

This combination of PDF/A-1, qualified electronic signatures and biometric signatures has won over several other radiation treatment centres, including the radiation oncology centres in Singen, Friedrichshafen, Greifswald and Berlin-Grunewald.

3.3. Legally compliant scanning with PDF/A and digital signature

Even though electronic diagnosis, documentation and communication methods are constantly gaining ground in all medical facilities, clinics and practices, a significant proportion of the documentation involved is still paper-based. Specialists estimate that the health care sector produces around 5 billion paper documents every year, leading to around € 2.5 billion in annual archiving and management costs. Every case of inpatient care produces around 50 documents, while each hospital bed produces around 1 meter in paper files per year. As an example, Braunschweig Clinic's archiving costs for the 3.5 million medical documents it produces each year run to around € 470,000, according to Christoph Seidel, the Clinic's head of IT and Business Development.

It's not just the vast quantity of documents that contribute to these extraordinary costs; the minimum retention period also plays a part. Most of the communication between the institutions and people involved in the treatment process is paper-based: treatment reports and discharge summaries, diagnoses and referrals start mounting up as soon as a patient walks into a clinic, is discharged or referred elsewhere.

The fact that so much of the information required for treatment is only available on paper has other consequences besides archiving and transport costs: the information is only ever available in one physical location, and has to be transferred or fetched from the archive before joint treatment, consultations or examinations. This takes both money and valuable time.

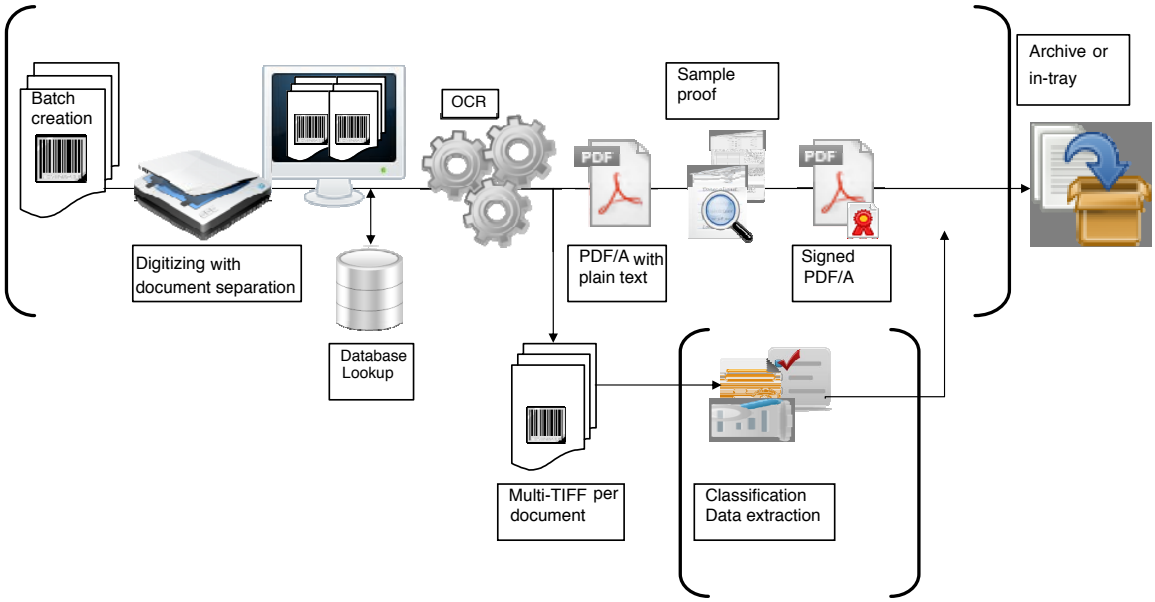
Incorporating digital patient records into hospital information systems is not only demonstrably cheaper for the purposes of long term archiving, communication and collaboration during treatment; there are several other advantages to being able to access the information from any location. Test results, diagnoses, medical images and administrative data are stored centrally and can be accessed simultaneously from different locations.

For this reason, an increasing proportion of detailed paper documents are being scanned and stored in centralised information, management or practice systems, where they can be pulled up at the click of a mouse. Leading medical IT experts expect the paper to keep mounting up in the health care sector for some time, particularly since the parties involved in developing the electronic health card have spent years at loggerheads over electronic exchange procedures.

There are two methods for archiving scanned documents, which complement each other brilliantly:

- converting the scanned images to PDF/A in accordance with ISO 19005, which provides the familiar benefits of being able to read the document on any operating system, full text search capabilities through the use of OCR and the ability to include explanatory metadata.
- Digital signatures, which guarantee the integrity, authenticity and inalterability of documents, and can be embedded in PDF/A to keep documents in electronic archives secure and self-explanatory.

These processes are explained in the illustration below (source: SRZ). One particularly secure and convenient method is scanning and signing documents in a single workflow at one workstation. This can be done in the mail room or one the premises of a qualified service provider.



3.4. Patient reception – scanning to PDF/A

A number of clinics and hospitals have been doing this successfully for years. The Philippusstift Clinic in Essen is one example.

As soon as a patient is received in the clinic, their paper-based records are scanned in. From that point on, they are available in digital form for doctors and nursing staff to pull up at every stage of the patient's treatment. PDF/A is a technologically advanced secure file format with significant advantages in terms of colour scanning and full text search capabilities based on a secure ISO standard.

It can be implemented in a number of ways:

- In terms of hardware, there are several cheap desktop scanners available which can be put at reception to save space. These can make high quality colour scans.
- Depending on the manufacturer, the scan client should be able to use OCR to allow full text search and instantly create a PDF/A.
- If not, lightweight tools are available which can handle tasks like compression, OCR and creating PDF/A files. These create highly compressed PDF/A files, which can then be incorporated into the workflow.
- Alternatively, a HIS system or DMS system might have a scan client that can be used at reception, allowing the staff to incorporate PDF/A files directly into the
- system. This alternative can be more complicated to implement, but has the advantage of integrating patient reception into the system.

The lightweight tools are easier to introduce and may simplify your workflow. The optimal solution will depend on the IT setup in each clinic. There are a number of solutions of this kind. Using PDF/A provides the following advantages:

- scanning in colour and optimal compression options
- standardised full text search capability using OCR
- documents can be optimised immediately in a secure ISO standard format.

Unlike old formats like TIFF and JPEG, PDF/A can also be displayed on any device and operating system, providing a number of options for mobile devices in the future.

3.5. Batch signatures for PDF/A documents

It is important for document management systems in the health care sector to be able to manage the

- marketability,
- long term stability,
- interoperability and semantic integrity

of medical content using efficient and simple use cases. Electronic signatures are a vital part of guaranteeing technical integrity, conformance with legislation and legal security. For archiving purposes, formats should be chosen which will continue to meet these requirements years down the line. It is also necessary for the processes involved to be as efficient as possible, so that they are accepted by users and provide clear added value in the day-to-day. IT doesn't make bad processes any better, so it's worth looking for opportunities to review familiar processes when introducing IT systems.

In our experience, PDF/A batch signatures meet all these requirements:

Users can unlock the content of their documents at the click of a mouse in the primary system or document management system. This can be done without inserting a card and entering a PIN, which would be enough for a single signature. Instead, the documents are converted to the long term archiving format PDF/A by a rendition service. Parallel formats like CDA XML or original formats can also be used in parallel. Files can be transformed between PDF/A and XML. This allows PDF/A-2 and PDF/A-1 files to provide important medical content for further processing instead of just being a static image.

At Heidelberg's Ethianum Clinic, documents are automatically combined with metadata in the digital signature folder by linking together the primary system and the document management system. Users can then sign some or all of the batch simply by putting in their card and entering their pin once, either at their own discretion or when instructed to. This is commonly done at the end of a day or after completing quality assurance on a folder or medical documentation. The DMAS checks whether there any technical issues with the PDF/A format beforehand. Users can review the content and appearance of their documents and send them to a workflow for correction if required.

The entire process is superior to paper-based processes from start to finish. The digital process also allows precise verification and ensures the long-term security of all documents. Providing they are converted directly to hash tree based structures, these documents will then be a self-contained record of all of the information along with an integrity and authenticity certificate.

4. The members of the SIG "PDF/A in Health Care"

4.1. About DMI

DMI is the leading provider of patient file/data archiving services. DMI has provided efficient solutions for archiving documents in line with auditing regulations since 1966. DMI is committed to being responsible for archiving patient data, so its processes for preparing and conducting reorganisations of archives are guaranteed to be successful. Investing in modern, cutting edge technology makes sense. DMI's expertise lies in value and potential analysis, archive reorganization, archiving systems, scanning services, document archiving and long-term digital archiving in compliance with auditing regulations. Over 650 customers, among them more than 500 hospitals, have put their trust in DMI's many years of experience. DMI processes around 1,000,000 document pages every day.

URL: www.dmi.de

4.2. About intarsys

intarsys GmbH is a renowned developer of high-quality, high-tech software products and components for creating and verifying qualified and advanced electronic signatures, secure authentication, timestamps and audit-proof long term archiving of digital documents with PDF/A. intarsys develops signature renewal solutions based on Archisoft in partnership with the Fraunhofer Institute for Secure Information Technology. All signature products are based on a kernel that has been Common Criteria EAL 3+ certified by the German Federal Office for Information Security. intarsys signature products support all signature cards and signature card readers currently available on the market in German-speaking countries, as well as the new electronic ID cards (nPA), electronic health professional cards (eHBA), the SuisseID card and many other international smart cards and hardware security modules (HSM). intarsys works closely together with Trust Centers and card operating system developers to improve the functionality of its products and ensure support for future signature cards.

Under the motto "smart secure signing", intarsys provides a modular software system and middleware components for all major operating systems used on client and server systems. It also provides innovative apps – cloud suite components – for use in web portals and for cloud computing. intarsys' modern products and consistent application of international standards guarantee flexibility and a safe investment. It also reduces the amount of time that its customers have to spend on incorporating its products.

intarsys products make paper-free process support a possibility in any sector, from waste management and health care through to the financial sector and government agencies. intarsys also offers tailored software products for fields with special requirements, such as scanning documents so that they can be used as evidence, secure email gateways and electronic invoicing. intarsys has years of experience working together with multiple renowned customers and partners, both domestically and abroad. All of them trust in intarsys' expertise and experience in the area of certificate-based solutions and PDF/A.

URL: www.intarsys.de

4.3. About Luratech

LuraTech delivers production software and document and data conversion solutions, along with bespoke services and outstanding support. Scanning service providers and other enterprises and organizations get the most out of production equipment when working with LuraTech. LuraTech's solutions achieve the same levels of automation and integration in document processing as other industries have demonstrated in their own production methods. LuraTech's solutions are easy to handle and require only a small amount of customisation and individual programming work to implement.

The LuraDocument PDF Compressor Enterprise is a production-oriented application for compression, conversion to PDF(/A), OCR, classification and form data extraction.

Since its foundation in 1995, LuraTech has been a leading provider of open and ISO-standards-based document and image compression solutions , including successful PDF, PDF/A and JPEG2000 products.

LuraTech participates actively in various associations, including the "Competence Center Standards und Normen" and in regional groups of the Association of Organization and Information Systems (VOI) and BITKOM. In addition, LuraTech is the initiator and founding member of the PDF/A Competence Center - a global association with more than 120 members.

The PDF Compressor is of particular use to the health care sector as a tool for digitising documents like patient records. The PDF Compressor can either be used internally, or scanning service providers can use it to create highly compressed PDF/A files from scanned documents. With the help of the Born Digital add-on, hospital information systems can use the PDF Compressor to automatically convert scanned and digital documents to PDF/A.

URL: www.luratech.com

4.4. About SRZ

The Satz-Rechen-Zentrum (SRZ) is a solution and service provider in Enterprise Content Management, specializing in electronic archiving and digital document creation. The most important strength of the business is the development of software solutions, by themselves or with partners, for efficient document creation and document management. Their newest product is the software solution "CROSSCAP", designed for scanning and optionally signing documents in an integrated workflow. The application is extremely simple and intuitive to use; the installation does not require a server and is easy and inexpensive to integrate. All creation solutions from the SRZ support output in PDF/A format, whether searchable with the associated text saved or as a pure facsimile PDF. The SRZ's solutions are built on years of experience: they have been successfully developing and marketing their own software solutions for scan and creation services for mass records creation, books and large format scanning, and digitalizing microfilm since 1986. They serve a wide variety of customers, from retail and the residential trade, industrial businesses, pharmaceutical companies and financial institutions to the public sector, libraries and archives.

The Satz-Rechen-Zentrum was founded in 1969 and also has long-standing and fundamental experience from numerous successful projects in the areas of cross media publishing. The company has around 90 employees in two service centres in Berlin and its sales support offices in Frankfurt and Stuttgart. The SRZ prepares and

distributes specialised information specifically for the health care sector (information related to the pharmaceuticals industry, the "Rote Liste" medicines compendium) and also provides document digitalisation services, as well as batch signing solutions. The SRZ also provides easy-to-use systems for digitising post using CROSSCAP®, including digital signature components for scanning and signing in a single workflow.

URL: www.srz.de, www.crosscap.de, www.pdfkorrektor.de

4.5. About secrypt

secrypt GmbH specializes in solutions for the optimization, acceleration and security of digital business processes with electronic signatures, time stamps and encryption that complies with statutory regulations. With its digiSeal® product family, the ISO 9001 certified company ensures the authenticity, tamper resistance and confidentiality of sensitive data inside an electronic archive, while maintaining its long term probative value.

The option for paper printing of electronically signed documents in a verifiable, legally binding manner gives secrypt a unique selling point worldwide.

The Berlin-based company provides tailored solutions and technologies for a variety of national and international applications to the industrial, retail, service, energy, health care and public sectors on the basis of its digiSeal® software portfolio.

URL: www.secrypt.de

4.6. About eHealthOpen

eHealthOpen Ltd. is a planning and consultation company for medical IT in clinics and hospitals, and also provides agency and corporate consulting services for marketing, product management and projects to the health care market. Its areas of expertise are

- eHealth platforms and apps
- digital archiving
- DMAS and ECM
- a pragmatic approach to electronic signatures
- organising the Schliersee conferences

Its areas of expertise cover all-inclusive consultancy related to introducing Enterprise Content Management/ECM, multimedia archives, eHealth applications, electronic patient records, social media, signature and archiving methods and legal services. It is also actively involved in standards organisations, including BITKOM, CCeSigG, GMDS and the PDF/A Competence Center. It also publishes guidelines and regulations, such as the Schliersee Memorandum on the Legal Force of Scanned Documents (Schliersee Memorandum zum ersetzenden Scannen) and integration in the areas of eHealth and DMASS

URL: www.ehealthopen.com