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Clinical Trial Information System (CTIS) Bitesize talk

Document and Personal Data in CTIS

Presented by Charalampos Drosos, Laura Pioppo and Sjennie Daelmans on 23 February 2023
European Medicines Agency

The European Medicines Agency developed this training material to enhance public access to information on the Clinical Trial Information System (CTIS). This material describes a preliminary version of CTIS and may therefore not entirely describe the system as it is at the time of use of this material. The Agency does not warrant or accept any liability in relation to the use (in part or in whole) or the interpretation of the information contained in this training material by third parties.

CTIS Bitesize talk:
Document and Personal Data in CTIS

14:30 - 14:35	**Introduction**
14:35 – 15:55	**Presentation, CTIS Demonstration Sessions followed by live Q&A Sessions**
15:55 – 16:00	**Closing remarks**

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A few housekeeping rule

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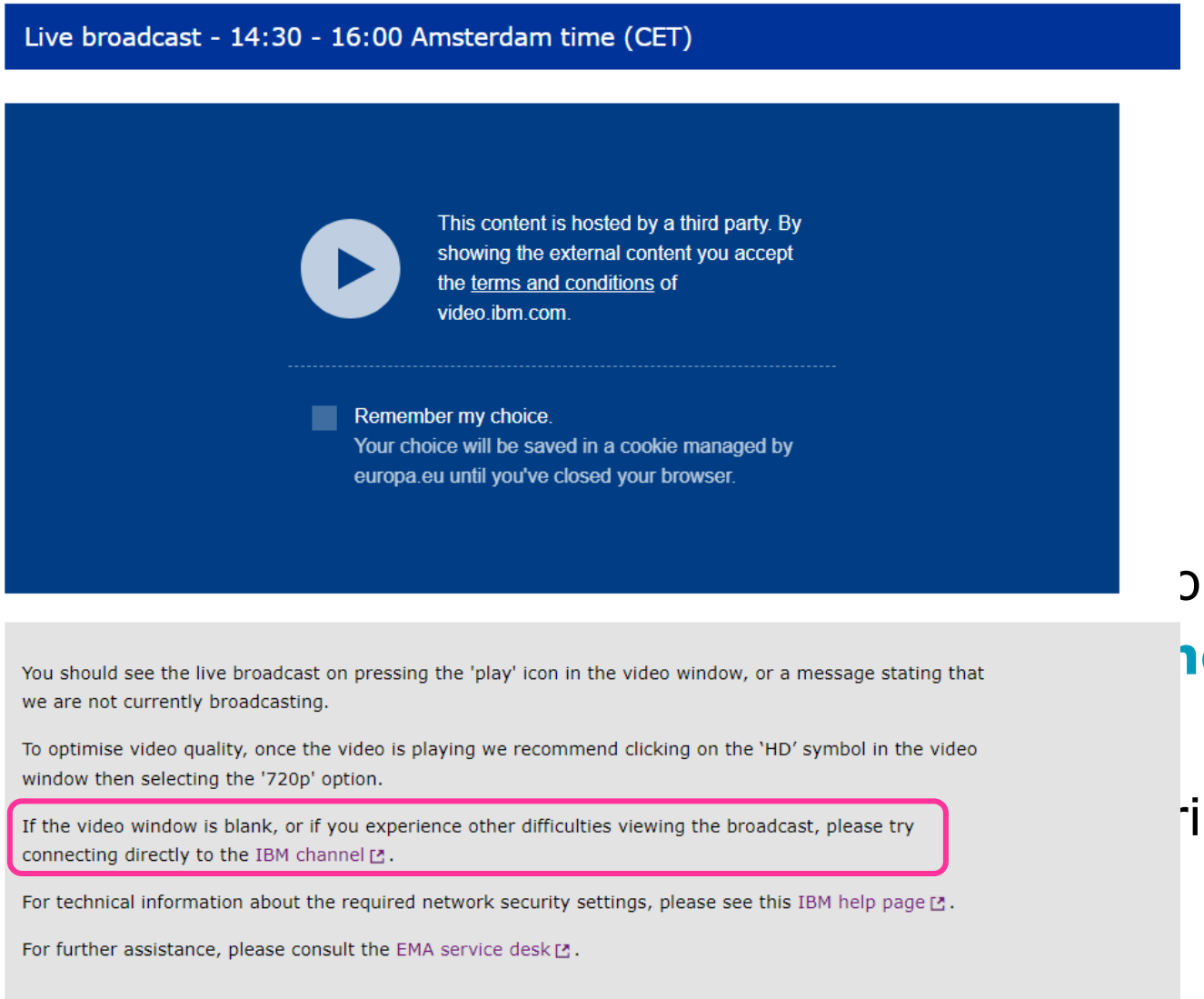
- Make use … the ever … o in … nel
- Increase … botto … right



Main Session: Document and Personal Data in CTIS

- Presentation
- Live demo with Q&A

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Sjennie Daelmans
Scientific Specialist

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Charalampos Drosos
CTIS Change Management Officer

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Laura Pioppo
Senior Scientific Specialist
Workstream lead

Documents and Personal Data in CTIS

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What is considered personal data?

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'Personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. (Article 4(1) of the GDPR and Article 3(1) of the EUDPR).

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Types of personal data:

- Direct identifiers: such as name, surname, signatures
- Indirect identifiers: such as role, affiliation, demographic data
- Pseudonymised data of trial participants (subject ID)

CTR and personal data

- GDPR / EUDPR applies to processing of personal data within CTIS
- CTIS shall contain personal data only insofar as this is necessary for enabling cooperation and communication between the different users - *Article 81(6) CTR*
- CTIS is to enable cooperation between the competent authorities of the MSs concerned to the extent that it is necessary for the application of the CTR and to search for specific clinical trials – *Article 81(2) CTR*
- CTIS shall be publicly accessible except where justified to protect the confidentiality of personal data - *Article 81(4) CTR*
- No personal data of subjects shall be publicly accessible - *Article 81(7) CTR*

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CTIS Joint Controllership Arrangement (JCA)

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Protection of personal data while using CTIS is the joint responsibility of:

- EMA
- European Commission
- EU/EEA Member States
- Commercial, non-commercial organisations and academia acting as sponsors of clinical trials and/or marketing authorisation applicants/holders

- Each party should ensure that personal data are treated according to the principles of the **GDPR** (for MS, sponsors, MAAs, MAHs) and **EUDPR** (for EMA and EC)
- A **Joint Controllership Arrangement** (**JCA**) has been created by the EC, EMA, EU/EEA Member States in consultation with representatives of industry associations, academia and learned societies. JCA contains **Annex II on Data protection notice**
- When accessing CTIS for the first time, users will be reminded of the contents of the JCA before they can progress with the use of CTIS.

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Roles and responsibilities

Protection of personal data in CTIS is a joint responsibility (see JCA)

Each party should ensure that personal data are processed according to the principles of the GDPR applicable to MSs, Sponsors, Marketing Authorisation Applicants/Holders (MAA/MAHs) and EUDPR applicable to EMA and EC

- Sponsors/applicants responsible for the content of uploaded CTA documentation
- MAAs/MAHs responsible for the content of the uploaded CSR
- MSs responsible for the content of the uploaded Assessment Reports and RFI
- EC responsible for the content of the Union Controls plans/programmes & reports
- EMA responsible for the users management within CTIS

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Publication Rules in CTIS

Article 81(4) of CTR outlines the requirements for transparency in CTIS:

"The EU database shall be publicly accessible unless, for all or part of the data and information contained therein, confidentiality is justified on any of the following grounds:

(a) protecting personal data in accordance with Regulation (EC) No 45/2001;

(b) protecting commercially confidential information, in particular through taking into account the status of the marketing authorisation for the medicinal product, unless there is an overriding public interest in disclosure;

(c) protecting confidential communication between Member States in relation to the preparation of the assessment report;

(d) ensuring effective supervision of the conduct of a clinical trial by Member States".

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Preventing publication of personal data

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Management of personal data in CTIS

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- CTIS allows to upload a document version '**for publication**' and '**not for publication**'
- **Personal data**, if needed during the scientific and regulatory review carried out by the Member States concerned, should be provided in the document version '**not for publication**' (e.g. sponsor personnel, details of the QP GMP and, exceptionally, pseudonymised data of trial participants)
- **Personal data** in the document version '**for publication**' **must be anonymised**, *with few exceptions*
- **Annex I** – of the draft guidance document on how to approach the protection of personal data and commercially confidential information in documents uploaded and published in the CTIS – contains an overview of documents submitted to CTIS and the types of personal data contained
- Please also consult Annex II of the JCA for an overview of personal data that are captured in CTIS

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Anonymisation of personal data - documents 'for publication'

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- **Anonymous data** - information which does not relate to an identified or identifiable natural person (Recital 26 of GDPR and Recital 16 of EUDPR)
- ***Individuals other than clinical trial participants***
  - Personal data must be anonymised in the version of documents 'for publication', this includes signatures
  - Exceptions
    - Name and surname of principal investigators, legal representative of the sponsors, head of the clinic/institution;
    - Name and surname (but not signatures) of the sponsor and coordinating investigator in the clinical study report and the identities of the principal investigator(s) who conducted the trial
- ***Clinical trial participants***
  - Must be anonymised in the version of documents 'for publication'
  - No exceptions

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What documents contain personal data in CTIS?

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- Personal data of trial participants, in pseudonymised format such as subject ID, if provided should be included in the document version '**not for publication**'
- Personal data of trial participants be anonymised in the document version 'for publication'
- This applies to any documents in CTIS which might contain these personal data for example: CTA dossier, notifications such as serious breaches, any assessment document produced by MSC, summary of results and CSR.

What documents contain personal data in CTIS? – cont'd

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[ACT EU_Q&A on protection of Commercially Confidential Information and personal data while using CTIS (europa.eu)]:

Only the name and surname of applicable persons are required on the following documents:

- Principal investigator on the CV;
- Qualified Person (QP) on the QP declaration;
- The person issuing the site suitability document;
- Data Safety Monitoring Board (DSMB) composition on the charter or applicable document;
- Minimum amount of sponsor staff in the protocol
- GDPR compliance statement to be provided under the CTIS 'form' section, in line with available template

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What documents contain personal data in CTIS? – cont'd

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Example: Investigator CV

Included (not limited):

- Principal Investigator name and surname
- Affiliation with the institution
- Current position
- Experience
- …

Template available in Eudralex Vol 10

Not included (not limited):

- Signature (with few exception by MSs, see Q&A)
- Private contact details
- List of publications including co-authors
- …

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CTA document properties

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Removal of personal information from properties of CTA documents

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- Users need to upload many documents, WORD files or PDF files, in their trials submitted via CTIS.
- After preparing the documents in their computers and before uploading them to their trials in CTIS, users need to **make sure that they have removed any personal information from the properties of their documents**.
- Users can follow some simple steps to remove the data from the properties of their documents.

Please consult Module 2 – '**Guide on CTIS Common features**' for step-by-step guidance on how to remove personal data from Word and PDF document properties

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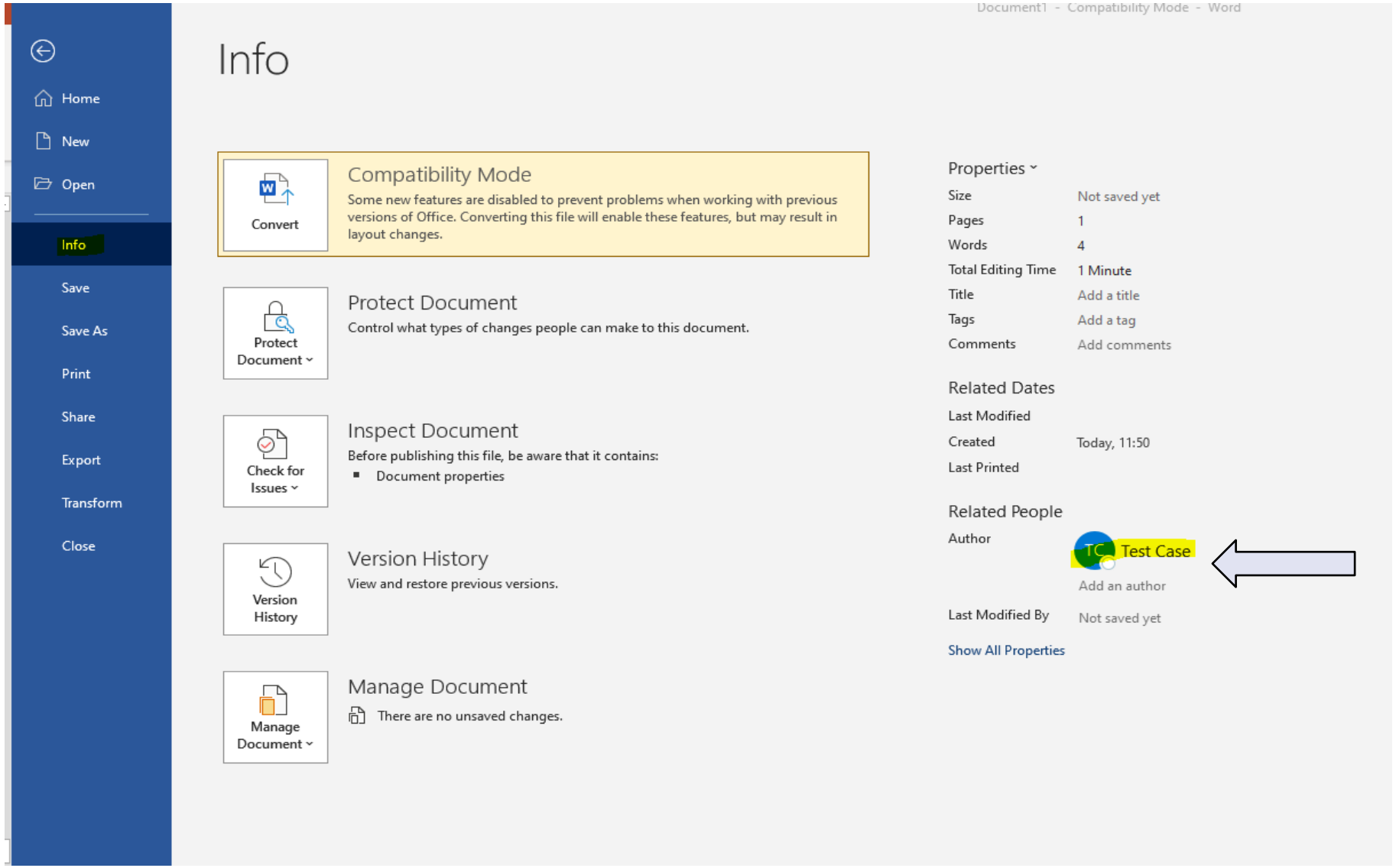

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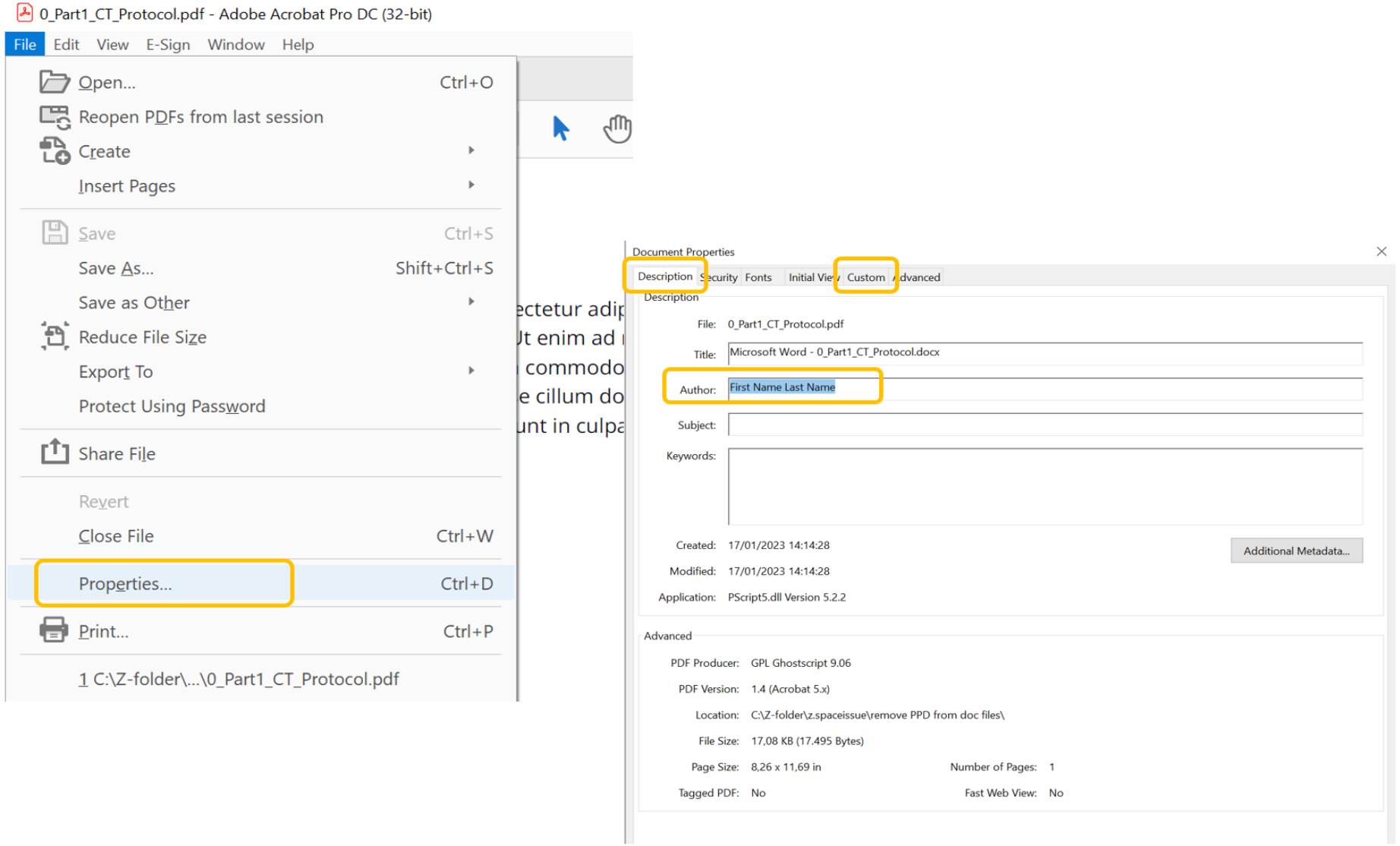

Demo and Q&A session

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We ask for *your feedback* on this event

A feedback **poll is now open** in Slido

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CTIS training environment Survey 4.0

Survey 4.0 remains open where new potential users of CTIS can express interest to access the CTIS training environment (CTIS Sandbox).

CTIS Sandbox Survey 4.0

For satisfaction feedback, Please go to ***www.sli.do*** *& use event code* ***#bt23feb***

CTIS upcoming events

- **CTIS Walk-in Clinic – 16 March 2023 – 16:00 – 17:00 CET**
- **CTIS Walk-in Clinic – 19 April 2023 – 15:00 – 16:00 CET** (more details will be available shortly on the CTIS training and support page)
- **CTIS Bitesize talk – 26 April 2023 – 14:30 – 16:00 CET** (more details will be available shortly on the CTIS training and support page)

For satisfaction feedback, Please go to ***www.sli.do*** *& use event code* ***#bt23feb***

Thank you for attending today's event

Further information

For the Clinical Trials Highlights sign up at CT.NewsletterSubscriptions@ema.europa.eu.

Latest CTIS Newsflash can be consulted here

For upcoming CTIS events, visit the EMA event page.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Telephone +31 (0)88 781 6000

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