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The EUCROF New Technologies Working Group (NTWG)

Code of Conduct team, eConsent team, Archiving team, Artificial Intelligence workshops with the EMA and the FDA

Chairman – Alan Yeomans
Deputy Chairman – Yoani Matsakis

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The EUCROF Code of Conduct for Data Protection in Clinical Trials

Team Leader – Yoani Matsakis

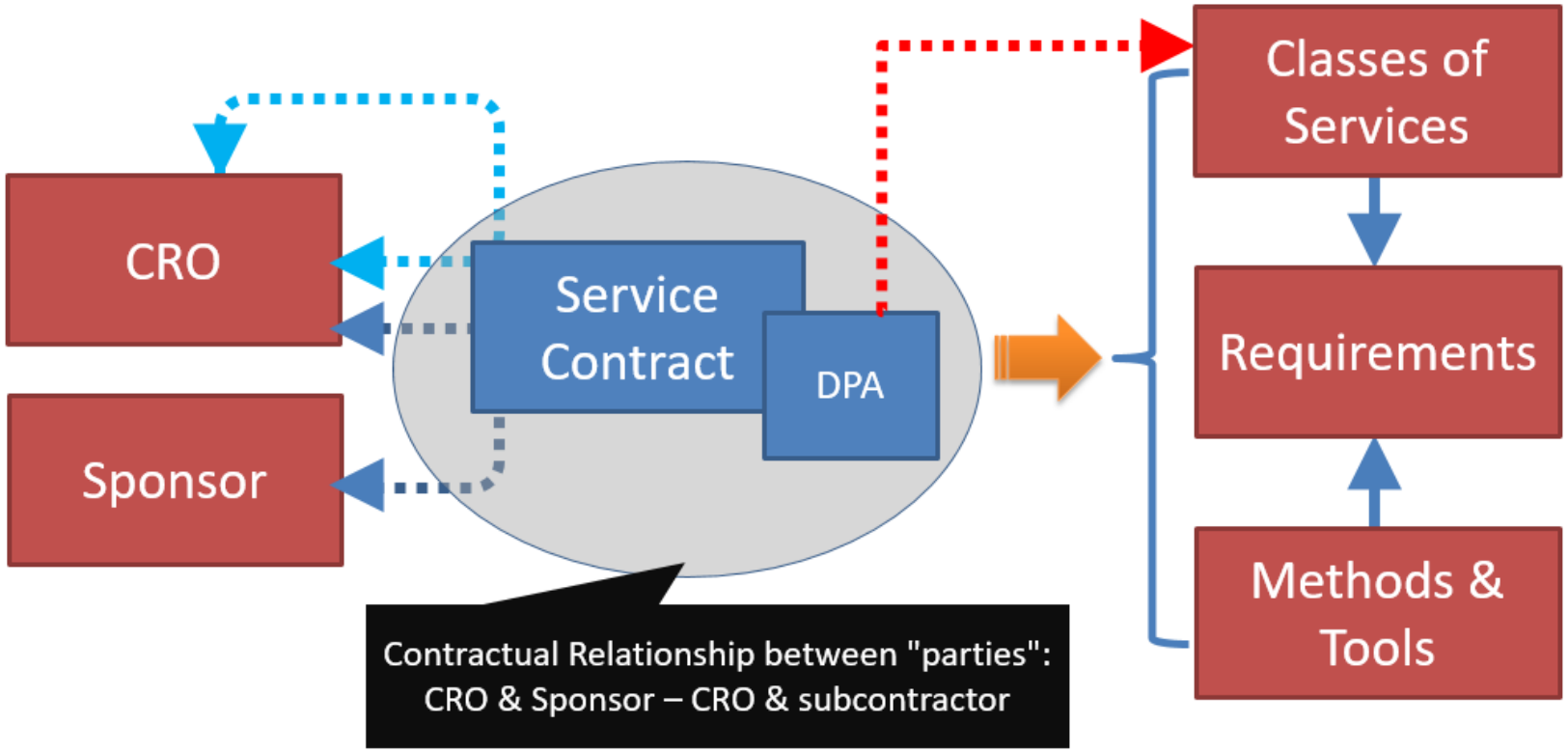
2 December 2020

Final Draft of the Master Document has been released and shared with the lead Data Protection Authority

Key features

- The EUCROF Code is made up of a set of documents.
- This set can only be considered in its entirety: none of these documents, taken in isolation, can be considered as constituting the Code:
  - Document "01" - "EUCROF Code of Conduct" including its appendixes, is the "master" document specifying all main features of the Code;
  - Document "02" - "Model of Data Processing Agreement – Controller/Processor";
  - Document "03" - "Model of Data Processing Agreement – Processor/Sub-processor"
  - Document "04" - "Requirements Specifications & Mapping with Classes of Services". This document is available both as PDF and as XLS file.
  - Document "05" - "Recommendations on legal basis and information to data subjects".
  - Document “06” - “Delivery of supplementary patient services in a study by a CRO”.
  - Document "07” - “Legal mechanisms for international transfer of personal data”.

The basis: a "Contractual relationship"



1. The "Service Contract"
2. The Data Processing Agreement (DPA) addressing Data Protection matters.

[1] The Code establishes a set of "requirements"

Master document	**92**
ISO 27001 requirements	**113**
HDH Requirements	**40**
	245

Document "04" lists all requirements and provides guidance on compliance methods for each requirement.

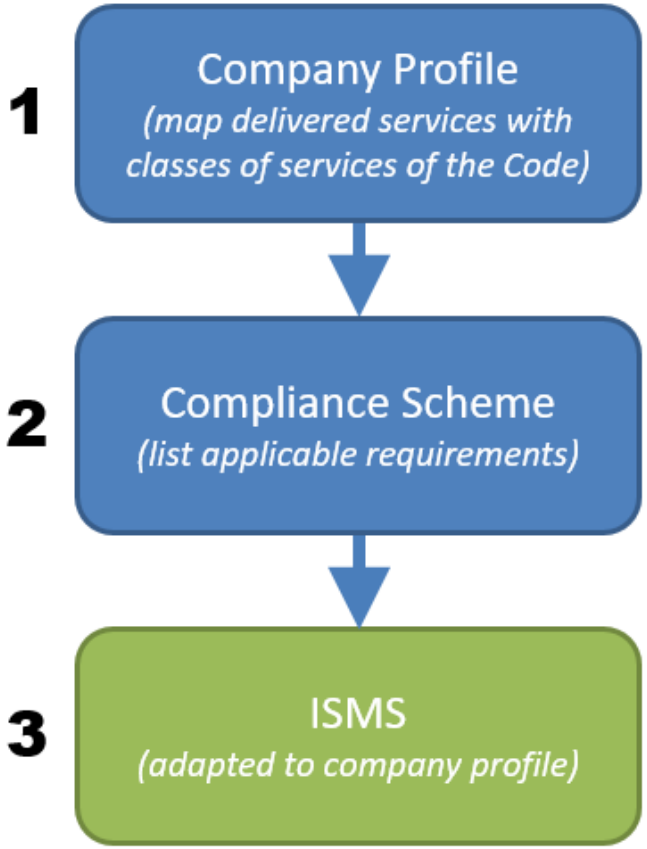
[2] The Code specifies a series of "classes of services" in it scope

(1) Synopsis, protocol and CRF design
(2) ICF design & information leaflet
(3) Site selection and contract
(4) Data collection
(5) Monitoring
(6) Medical monitoring
(7) Pharmacovigilance (PV) and Safety Reporting
(8) Patient services
(9) Data management
(10) Statistical Analysis
(11) Clinical Study Report (CSR)
(12) Financial Management
(13) Public Disclosure
(14) Translation of study documents/data
(15) Audits
(16) IT Managed Services
(17) Provision of Physical Infrastructure
(18) User / Technical support & Hotline
(19) Decommissioning services
(20) Maintenance of Trial Master File
(21) Archiving Services
(22) Regulatory / Study start-up Services
(23) Arrangement of Investigator Meetings

A CRO adheres to the Code when it demonstrates compliance with all requirements mapped with the services it delivers.

Document "04" provides a mapping of Classes of Services with corresponding applicable requirements.

A Compliance Scheme adapted to each "company profile"



- For SMEs as defined by the EU

  See https://ec.europa.eu/growth/smes/sme-definition_en.

- Map services with requirements to define "compliance" scheme

Services / Size	Class of Service 1	Class of Service 2	Class of Service 3	…	Class of Service 20
SME	Yes	No	Yes		No
~~Not SME~~	--	--	--	--	--

Some Key Features

1. Compliance makes it mandatory to establish an ISMS

   Information Security Management System;

   Can be designed as a complement of ISO 9001:2015 QMS

2. Model DPA mandatory for Processor / Sub-processor relationship
3. CROs providing class 16 (IT Managed Services) and 17 (Provision of IT infrastructure) services with hosting of clinical data and "large" CROs (not SME) must be ISO 27001 certified
4. Adherence to the Code has the same effect as standard contractual clauses or binding corporate rules, provided that all Parties involved in the international transfer are adhering to the Code;

Next steps

- Deliver final draft in English and French;
- Formal introduction into the "formal" approval process by all EU Member states Data Protection Authorities & follow-up;
- Promoting the Code towards internal / external stakeholders:
  - Webinar to all EUCROF affiliates and stakeholders;
  - External reviewers about this milestone (EFPIA, ACRO …);
- Encourage usage of EUCROF Code documents from now;
- Setup of governance body: onboarding other stakeholders (patient associations representatives …), dedicated SOPs, budget & financials;
- Implement EUCROF Code into our CRO IT Platform ….

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eConsent

Team Leaders – Fiona Maini, Mika Lindroos

EUCROF eConsent team

Team Composition

- CROs, Sponsors, Vendors
- Also interviews and engagement with other stakeholders

Activities

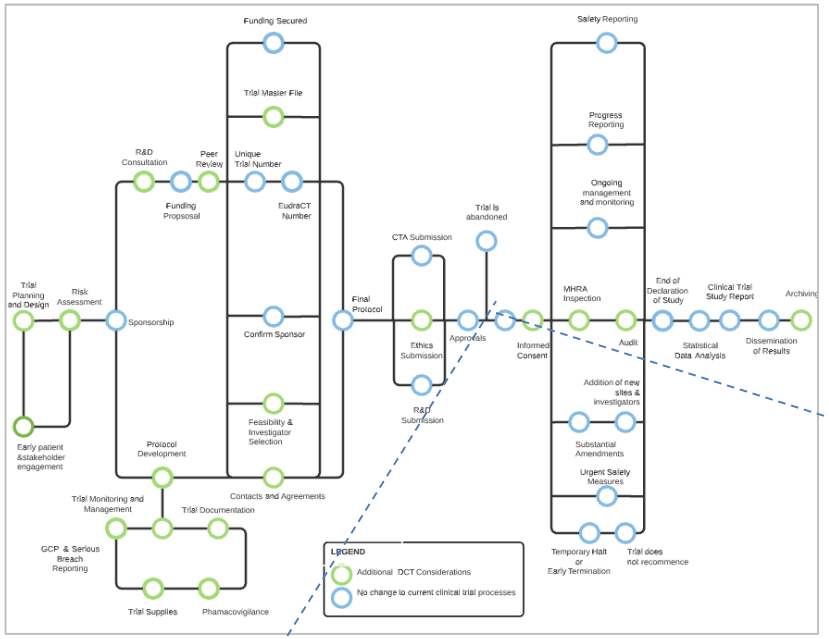
- Key deliverables & access to SMEs
- To provide insight and knowledge sharing around eConsent through:
  - Webinars – completed June and November 2020
  - eConsent Practical Implementation Guideline
  - Engagement with wider industry and authorities
  - Provide a ‘sounding board’ & forum for discussion & access to subject matter experts

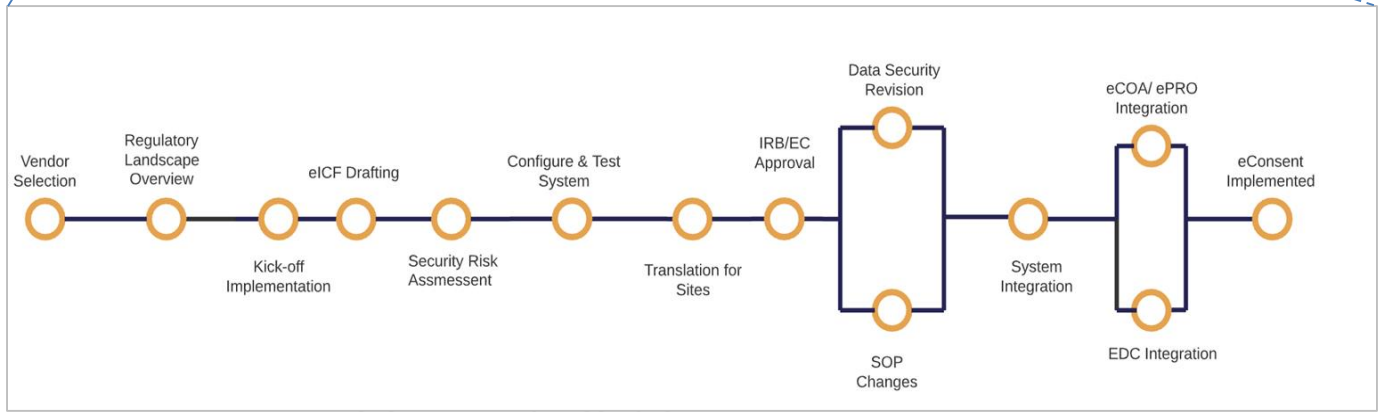
eConsent Paper Framework

Project Completion Timeline

ASSIGNMENT	19/10/2020	26/10/2020	2/11/20	9/11/20	16/11/2020	23/11/2020	30/11/20	7/12/20	14/12/2020
Framework Discussion									
Webinar Organisation									
Section Role Allocation									
Section Drafting									
Infographics Development									
Document Formating									
Draft					16/11/2020				
Review									
Final Version									
Webinar							30/11/2020		
Publication									

eConsent Implementation Process





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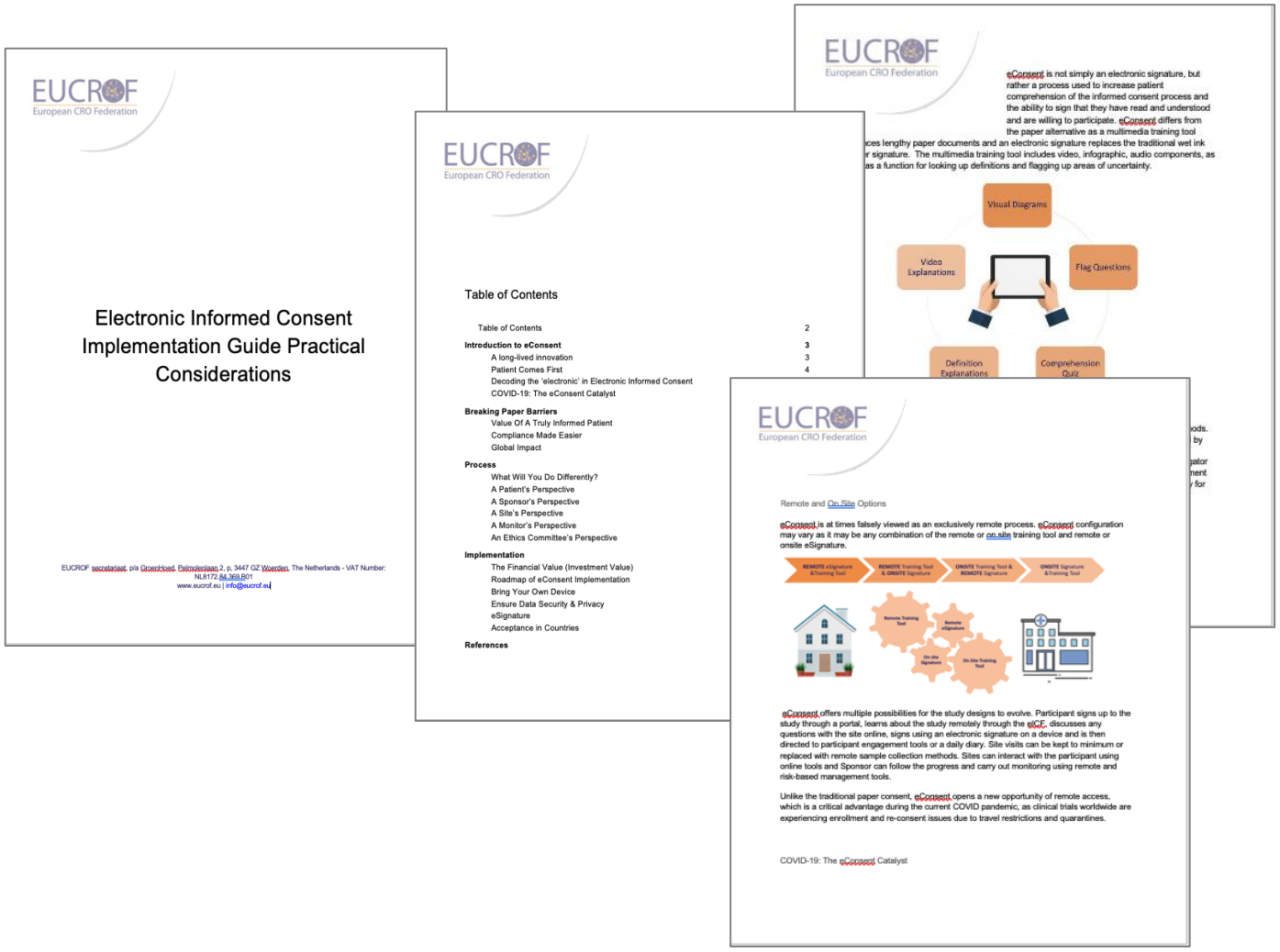
eConsent Implementation Guide



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Archiving and Decommissioning Position Paper

Team Leader – Alan Yeomans

Archiving team

- A joint EUCROF / eClinical Forum team
- Formed after discussions with the EMA GCP IWG at workshops they have invited us to in London and Bonn
- Scope is to present industry view on archiving of electronic essential documents/data and computerized systems
- At present two members from EUCROF (Alan and Dagmar), 14 from the eClinical Forum, and members representing the ePRO consortium, RQA, ECRIN and Medicines for Europe

The Positions

The sponsor should define and implement the index of essential documents for their trial
The same rules apply to all essential documents in a decentralized TMF for which the sponsor and the investigator have distributed accountabilities
It is the responsibility of the sponsor to ensure via contractual agreements with all parties that essential documents are readily available and accessible for audits and inspections during the retention period
Risk assessments covering data retention threats such as acquisitions, bankruptcies and technology obsolescence shall be performed, and mitigations will be documented in an archiving plan
There needs to be a periodic check of the archives to confirm continued viability
There are archivist duties required within all organizations (sponsor, CROs, investigators, and trusted third parties) managing parts of a decentralized TMF
Sites may decide to use Trusted Third Parties (TTPs) to archive some / all essential documents
Only the aggregated data that comes from IoMT need be retained as source
Transient data from patient user devices becomes source when migrated to the clinical trial database
Essential documents must be migrated into appropriate archive formats
Electronic trial systems which are no longer being used in a trial are not required to be maintained in a (live) transactional state for the full retention period

Next Steps

- Draft version of a position paper that lists each position with approximately one page of justification for each
  - First review round of Position Paper – now completed
  - Second review round – started 2020-12-09
  - Comments will be requested to be returned by Friday the 15th of January at the latest, so that the final document can be compile and released by the end of January.
- We will start preparing slide deck that can be used for presentations of the positions at webinars and conferences next year.
- We will also prepare 2 or more detailed white papers on individual positions or subgroups of positions, starting with the ones we feel are the most controversial. Hopefully this work will be done by next summer.

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Artificial Intelligence Workshop

Artificial intelligence in clinical trials – ensuring it is fit for purpose

Background

- At the 2019 SCDM conference in Baltimore Lisbeth Breghnøj (EMA), Ni Khin (FDA) and the SCDM leadership spawned the idea of an interested parties meeting in Amsterdam to discuss the validation of AI
- After the 2020 EU Conference in Clinical Research in Amsterdam, Lisbeth reached out to EUCROF and the eClinical Forum saying that the GCP IWG e-sub-Group would like *"…to have our 'own' usual interested parties strongly represented*")
- A programme committee was setup to organise the workshop, comprising of members from the EMA, FDA, other regulatory bodies and 3 representatives from the SCDM (with a largely US focus), and 3 representatives from EUCROF and the eClinical Forum (with an EU focus) invited by the EMA
- The COVID-19 pandemic changed the focus and the scope of the workshop to be a virtual meeting. The meeting was planned for late afternoon EU time and limited to 5 and a half hours to enable participation from both coasts of the US
- The meeting became an introductory session setting the scene for a possible face-to-face workshop to be held in 2021

Comments from the regulators after the meeting on September 22nd

- *"I would like to especially thank the moderators (and your presenters) for the really great presentations, which definitely increased my appetite for a sequel"*
- *"I have noted a number of things that would require more follow-up"*
- *"I really hope that we can secure hosting for a 2021 follow-up meeting where we maybe can go somewhat deeper into fewer cases"*
- *"You did an excellent work of identifying very good speakers, putting together a very interesting agenda"*
- *"The current exchange, especially with regard to processes and applications, helped to have a more realistic picture of the documentation to be expected, so that the assessment of AI remains possible and proportionate"*

Next Steps

- Producing a summary document of the presentations from the last workshop
- Next meeting to discuss summary document on December 15th
- Planning for a new virtual workshop 2021, followed by a face-to-face meeting in Amsterdam later in the year when/if that becomes possible
- First planning meeting held in November, next planning meeting in January
- Alan continues to represent EUCROF on the planning committee