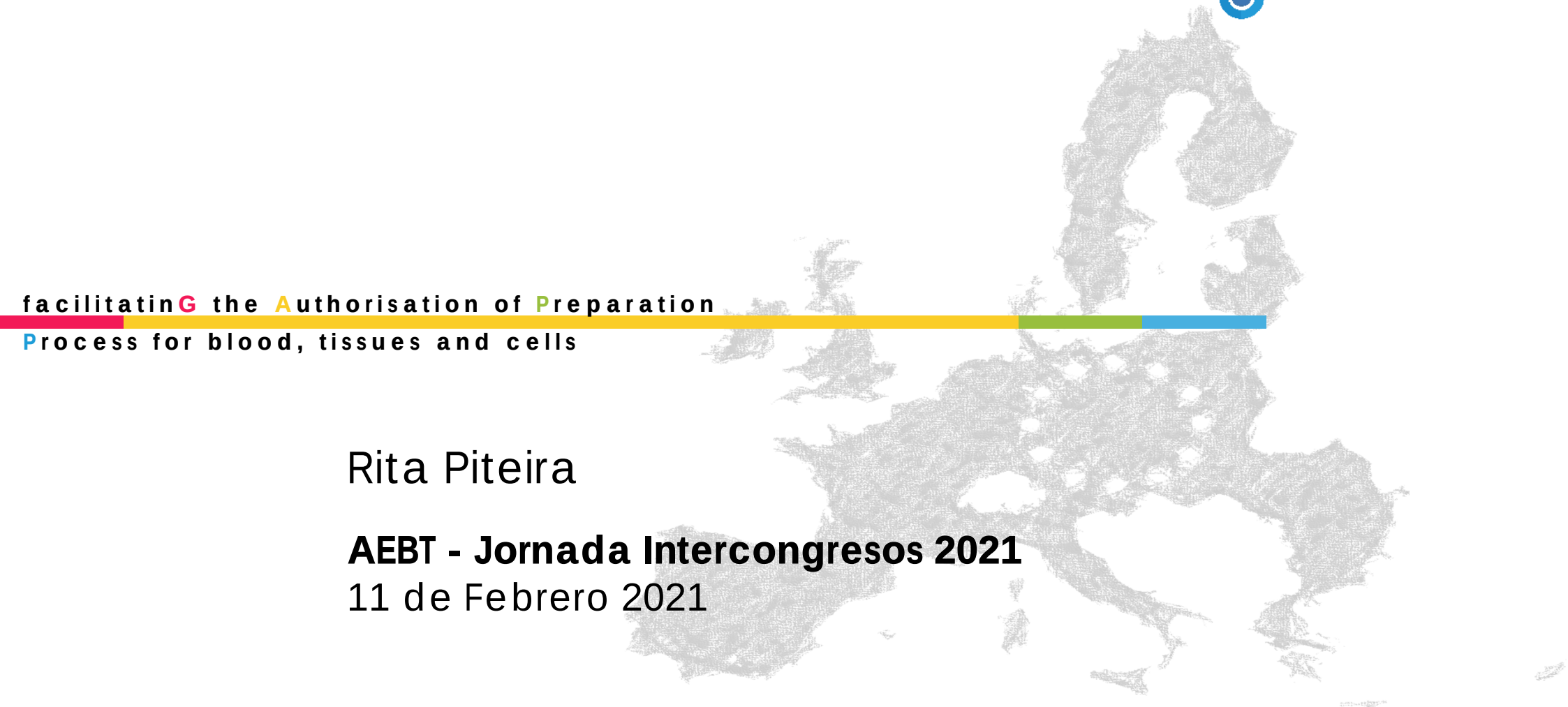
facilitatinG the Authorisation of Preparation Process for blood, tissues and cells



Rita Piteira

AEBT - Jornada Intercongresos 2021

11 de Febrero 2021

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Joint Action Beneficiaries

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1.
AMBITO Y CONTEXTO

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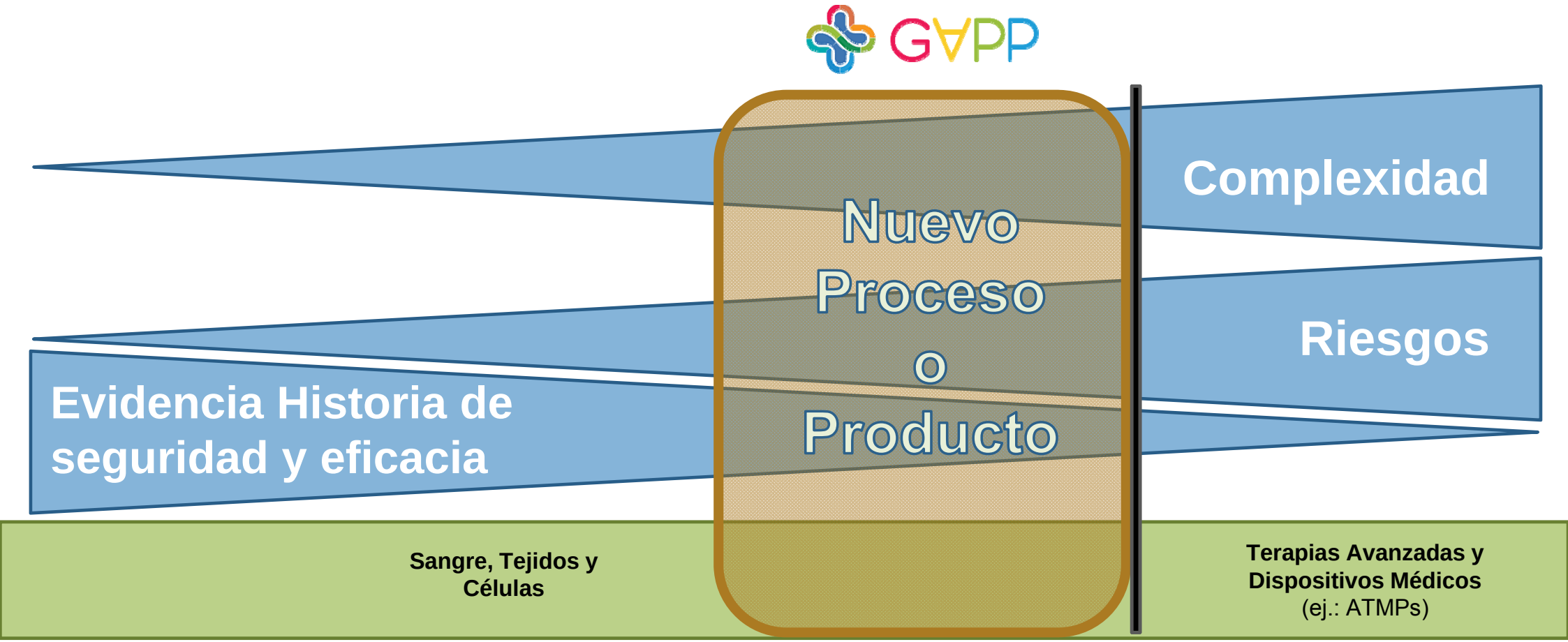
Adaptado de:

European Commission



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Adaptado de:

European Commission

GAPP

EUSTITE

EURO GTP II
Good Tissue & cell Practices

VISTART
VIGILANCE AND INSPECTION FOR THE SAFETY OF TRANSFUSION ASSISTED REPRODUCTION AND TRANSPLANTATION

Autorización Adaptada

Sangre, Tejidos y Células

Novedoso

Terapias Avanzadas y Dispositivos Médicos
(ej.: ATMPs)

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GAPP

Adaptado de:

European Commission

VISTART
VIGILANCE AND INSPECTION FOR THE SAFETY OF TRANSFUSION ASSISTED REPRODUCTION AND TRANSPLANTATION

EURO GTP II
Good Tissue & cell Practices

- Actualización del PPD y metodologías asociadas a la evaluación y autorización de **procesos de preparación** de Sangre, tejidos y células (BTC)

- Principios para la evolución y autorización de **nuevos** productos y terapias
  - Criterios y niveles de novedad
  - Evaluación de **Datos clínicos**

- Metodologías y herramientas:
  - Identificar lo que es novedoso
  - Evaluar el riesgo asociado a los nuevos procesos/productos y terapias
  - Propone la extensión de estudios necesarios para reducir el riesgo:
    - In vitro
    - In vivo
    - Evaluación clínica (follow-up)

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2.
OBJECTIVOS

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Enfoque metodológico común para el procedimiento de autorización, que podría ser tenido **en cuenta por la futura legislación de la UE**.

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3.
RESULTADOS

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WP1: Coordination & Management

WP2: Dissemination & Communication

WP3: Evaluation

WP4: Integration & Sustainability

WP5: Development of Overall Guidance on organization of PPA system

WP6: Authorisation of changes in donation, procurement and collection, processing, preservation, storage and distribution

WP7: Assessing the quality and safety of donor testing, microbial inactivation and sterilisation steps as part of PPA

WP8: Assessing clinical data as part of PPA

WP9: Knowledge sharing on PPA between EU CAs

WP10: Training

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Evaluación de las pruebas de enfermedades infecciosas, microbiológicas, y métodos de reducción de patógenos y esterilización

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D7.1. Table of contents – Annex II

Contents

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Componente Clínica del PPD

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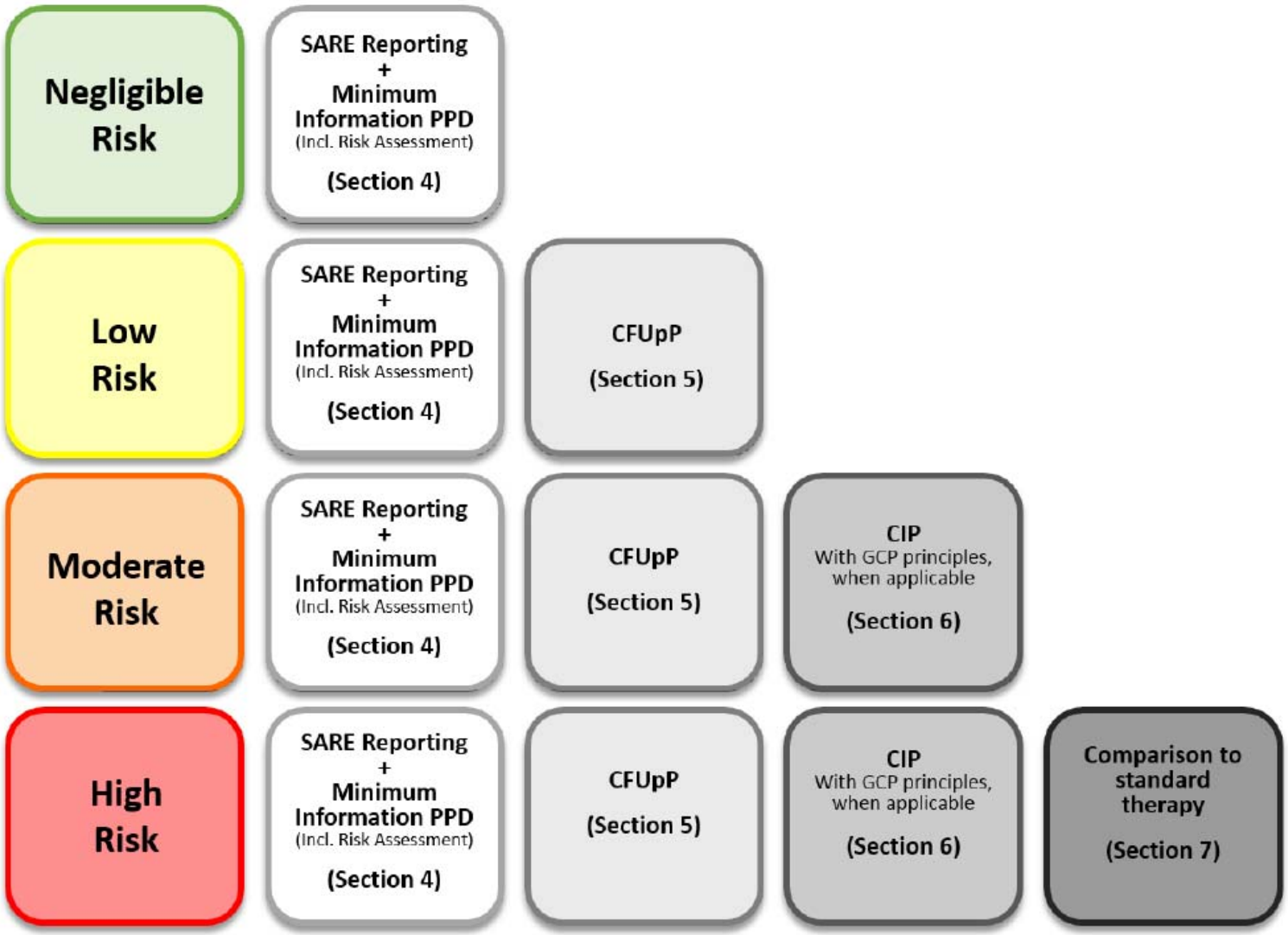
D8.3. Table of contents – Annex III

Contents



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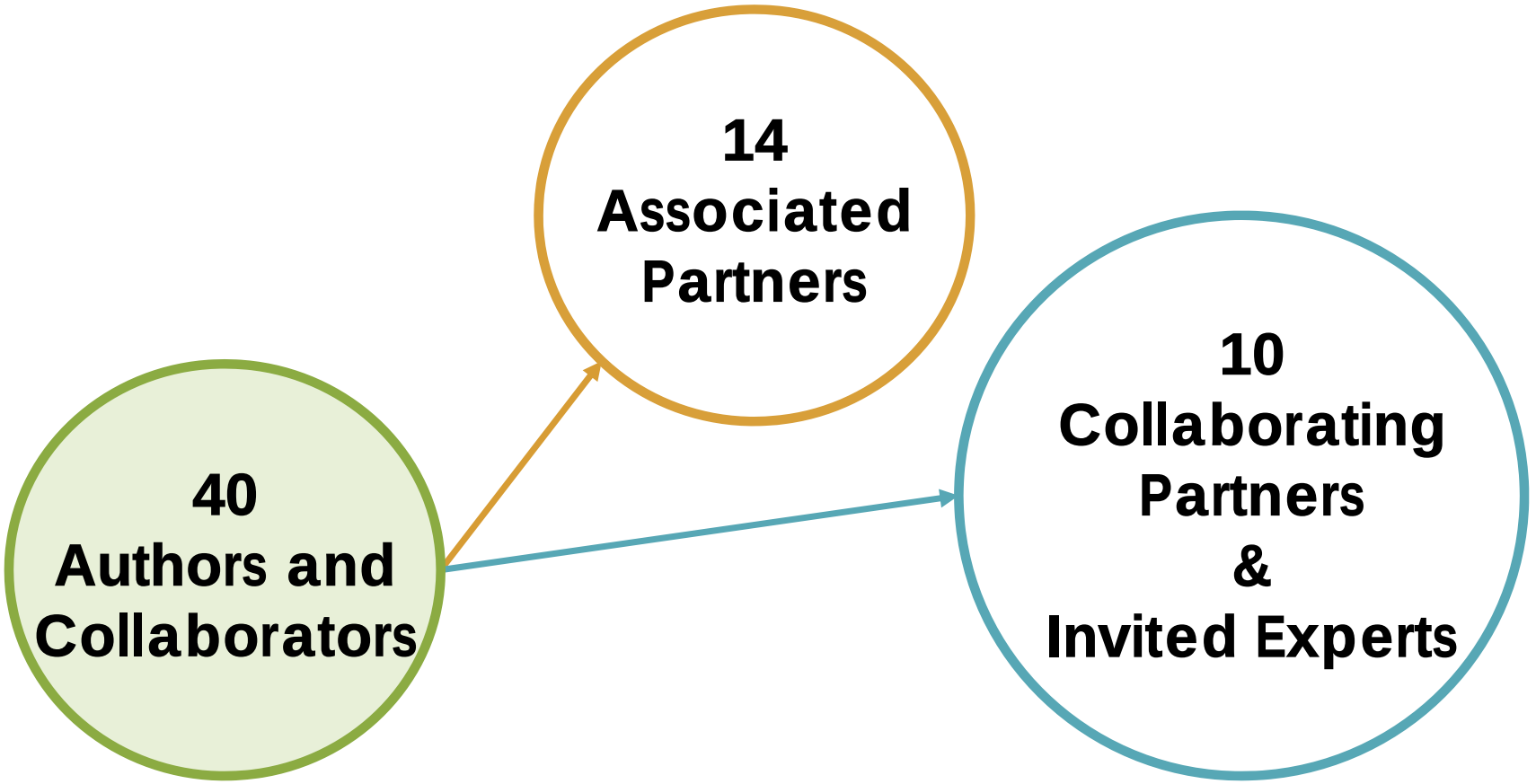
D8.3. Authors and Collaborators



EBMT
European Society for Blood and Marrow Transplantation

eshre
SCIENCE MOVING PEOPLE MOVING SCIENCE

EUROPEAN EYE BANK ASSOCIATION
EEBA

eba
EUROPEAN BLOOD ALLIANCE

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4.
CONSLUSIONES

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Lo que podemos esperar de los resultados de GAPP?

- No son de uso obligatorio, pero representan una nueva oportunidad para obtener reconocimiento mutuo y transparencia entre EM y ACs;
- Los requisitos definidos estarán alineados con la Guía EDQM y proyectos Europeos anteriores;
- El aumento del nivel de evaluación técnica permitirá mejorar las evidencias científicas asociadas a las actividades de los BT y centros implantadores;
- Los expertos serán invitados a colaborar con las ACs en las evaluaciones técnicas de las actividades y resultados clínicos.

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WP5: Overall Guidance on organization of PPA system

WP6: Authorisation of changes in donation, procurement and collection, processing, preservation, storage and distribution

WP7: Assessing the quality and safety of donor testing, microbial inactivation and sterilisation steps as part of PPA

WP8: Assessing clinical data as part of PPA

WP9: Knowledge sharing on PPA between EU CAs

Enero 2022

(Abril 2021)

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Barcelona Tissue Bank
Banc de Sang i Teixits

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