

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

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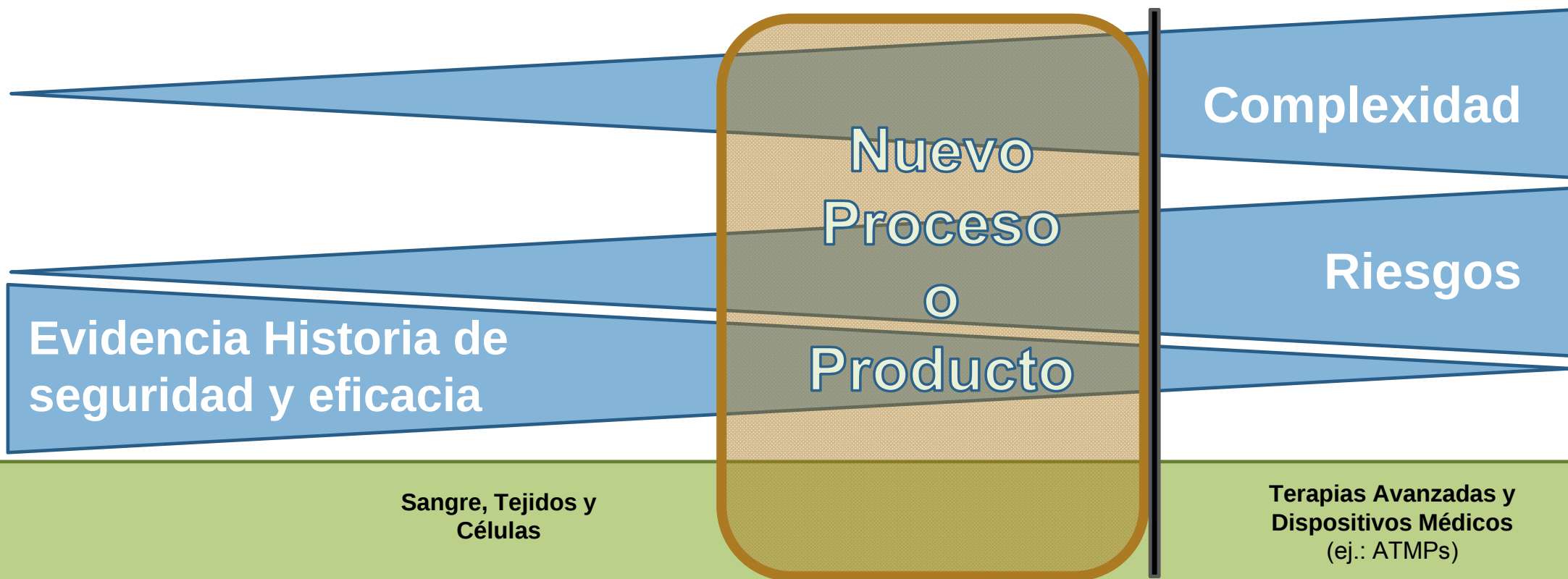
Joint Action Beneficiaries



1.

AMBITO Y CONTEXTO

Adaptado de:



Adaptado de:



**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)**



- ▷ 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**



**EURO
GTP II**

Good Tissue
& cell Practices

Adaptado de:



- ▷ 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)

2.

OBJECTIVOS



Requisitos
técnicos,
informaciones y
datos “mínimos”

Evaluación
estándar

Armonización y
Cooperación
Europea

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

3. RESULTADOS

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

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

D7.1. Table of contents – Annex II

Contents

1. General validation requirements
2. **Requirements and criteria for laboratories performing donor infectious disease testing and microbiological testing of BTC**
 - 2.1. Testing and screening of donors
 - 2.2. Quality system
 - 2.3. Standard
 - 2.4. Accreditation, designation, authorisation or licensing of laboratory by competent authorities
 - 2.5. Information on testing laboratories
3. **Requirements for selection, validation and performance of donor infectious disease marker testing kits and other methods**
 - 3.1. Selection of donor infectious marker testing kits and other methods
 - 3.2. Validation of donor infectious marker testing kits and other methods
 - 3.3. Performance of donor infectious marker testing kits and other methods
 - 3.4. Donor testing of emerging infectious agents
 - 3.5. Information on donor infectious disease marker testing kits
4. **Criteria for validation of pathogen reduction steps**
 - 4.1. Validation requirements depend on the type of PRT
 - 4.2. Aspects of PRT validation
 - 4.3. Validation criteria
 - 4.4. Methods for control of microbiological quality
 - 4.5. Effect of PRT on BTC quality
5. **Criteria for validation of sterilisation methods**
 - 5.1. Objects of sterilisation
 - 5.2. Sterilisation methods
 - 5.3. General validation requirements for sterilisation
 - 5.4. Specific validation criteria for sterilisation methods
 - 5.5. Information on sterilisation validation
 - 5.6. Effect of sterilisation on tissue quality
6. **Requirements and criteria for microbiological quality of the final BTC product**
 - 6.1. Common requirements applicable to all BTC
 - 6.2. Specific requirements and criteria depending on the type of BTC processing

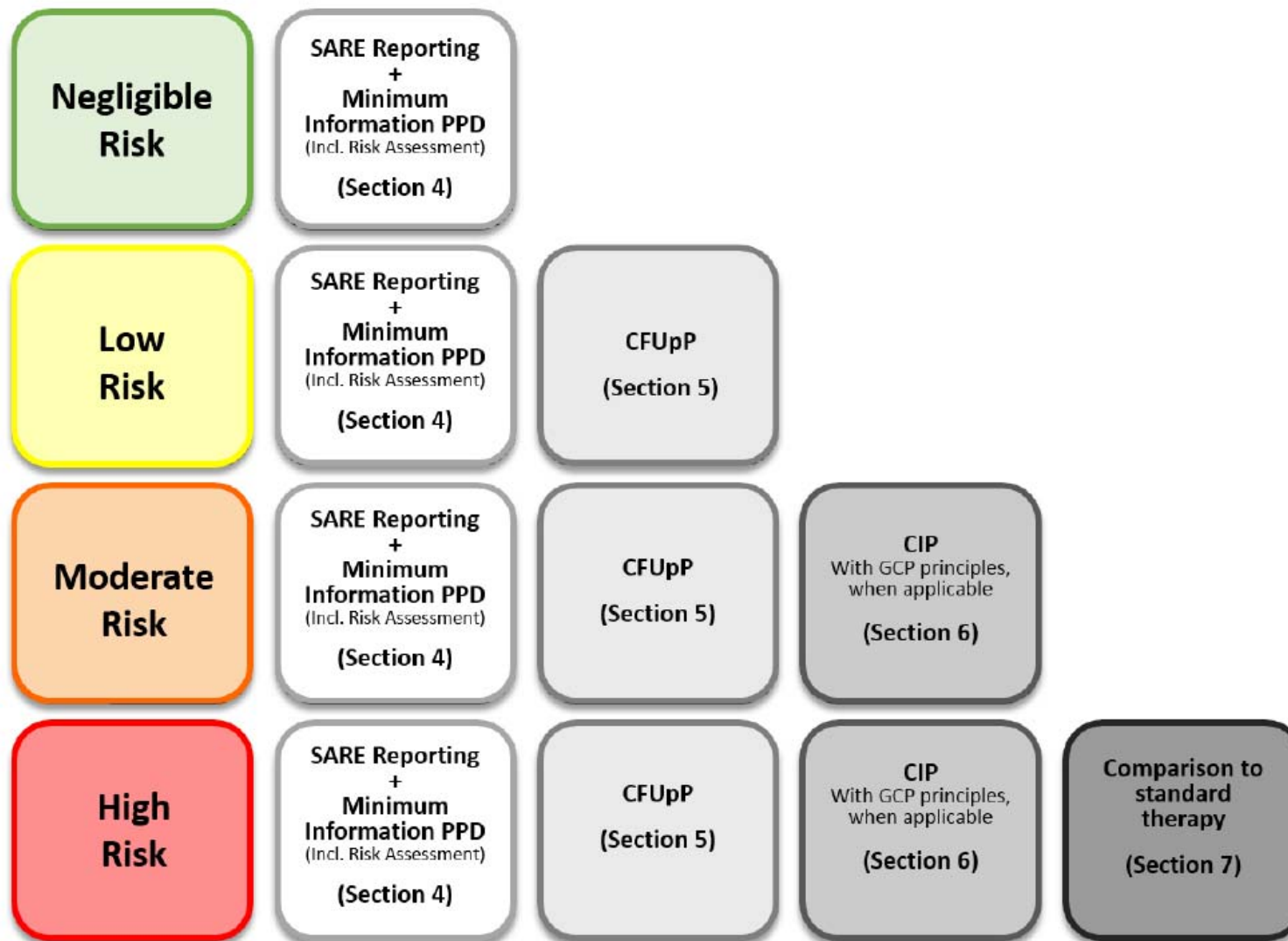
Componente Clínica del PPD

D8.3. Table of contents – Annex III

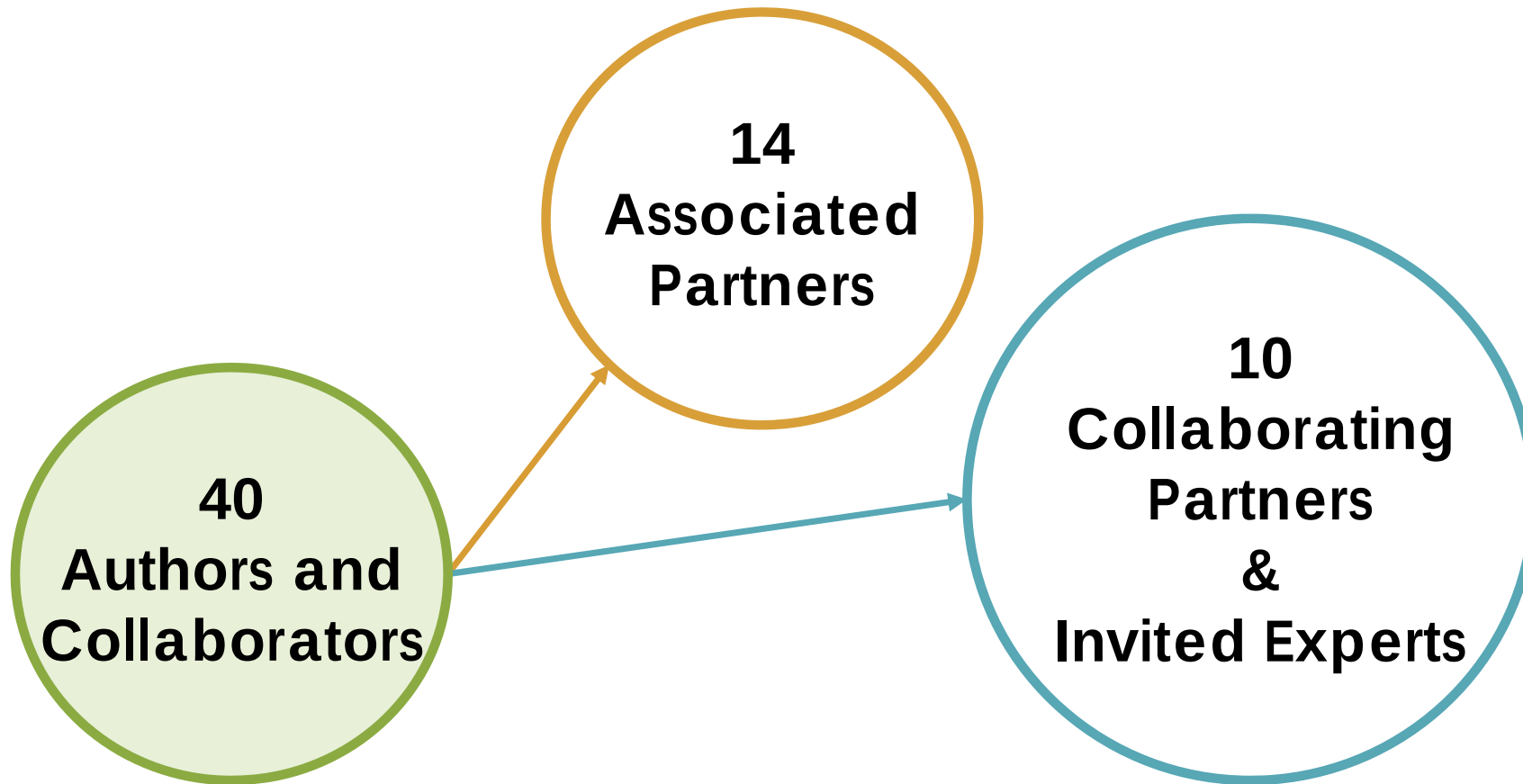
Contents

1. Introduction
 - Aim
 - Scope
2. The extent of the plan for collecting clinical data should be **based on risk assessment**
3. **Clinical data sources and types**
 - 3.1. Clinical data generated and held by the BE/TE and clinicians
 - 3.2. Clinical data in scientific publications
 - 3.3. Real-World Data
4. **Minimum information** of the clinical component of the PPD
 - 4.1. General information
 - 4.2. Clinical indication(s)
 - 4.3. Application/administration method(s)
5. **Assessment of Clinical Follow-Up Plan (CFUpP)**
 - 5.1. Clinical safety data
 - 5.2. Clinical efficacy data
 - 5.3. Duration of the clinical follow-up
6. **Assessment of Clinical Investigation Plan (CIP)**
 - 6.1. GCP principles
 - 6.2. Independent Ethics Committee (IEC) decisions/opinions
 - 6.3. Recruitment procedures and informed consent process of the recipients
 - 6.4. Insurance
 - 6.5. Inclusion and exclusion criteria
 - 6.6. Clinical endpoints
 - 6.7. Planned follow-up procedures, samples and/or visits of the recipients
 - 6.8. Methods for data collecting
 - 6.9. Multicenter investigations
 - 6.10. Data protection and data integrity
 - 6.11. Analysis of the clinical data
 - 6.12. Discontinuation/termination criteria
 - 6.13. Periodic and final reports
 - 6.14. Appendices required to support PPA
7. **Control treatment(s) for CIP with high risk level**
8. Updates and amendments
9. Discussion
- Bibliography
- Acronyms
- Definitions
- Annex I - Good practices of clinical setting for BTC
- Annex II - List of authors and collaborators





D8.3. Authors and Collaborators



4. CONSLUSIONES

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.

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



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Barcelona Tissue Bank

BANC DE SANG I TEIXITS