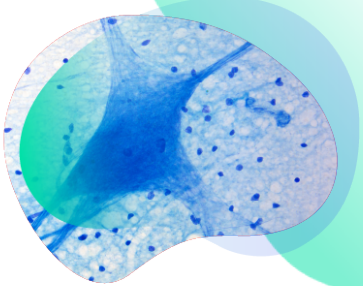
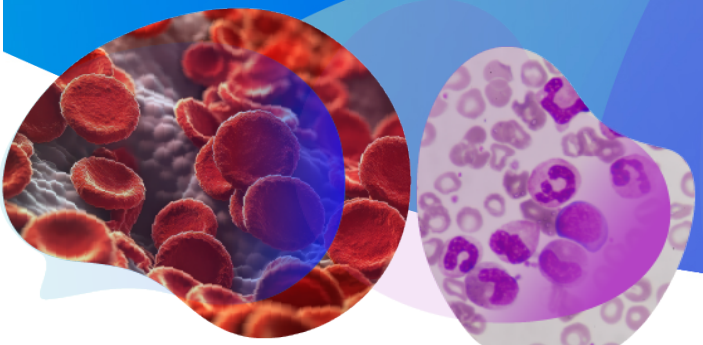
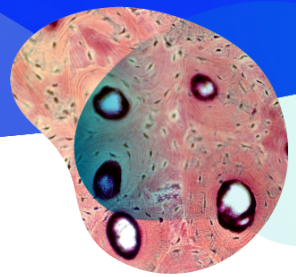


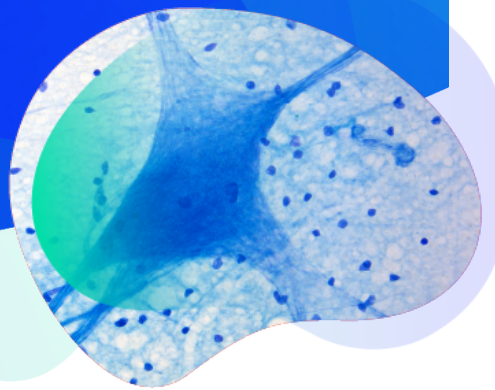
Giuseppe Feltrin

National Transplant Centre (Italy)

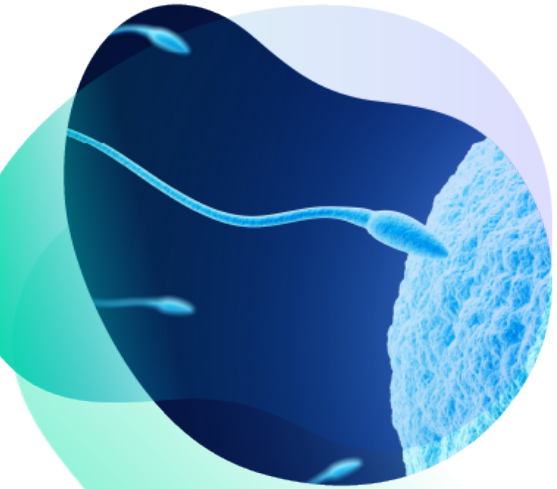
SoHO CONFERENCE • 24 I 06 I 2024 Brussels





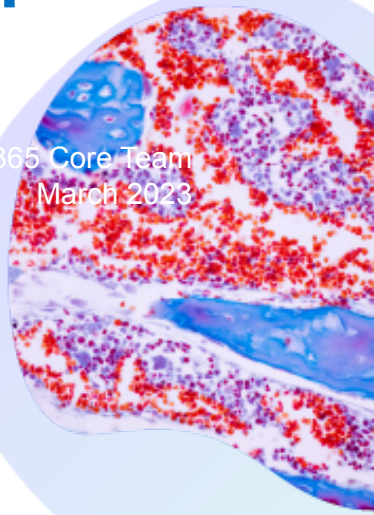


EUROPEAN HEALTH UNION



Giuseppe Feltrin (CNT), Vincenzo De Angelis (CNS)

Authorisation of SoHO preparation processes
- based on clinical evidence



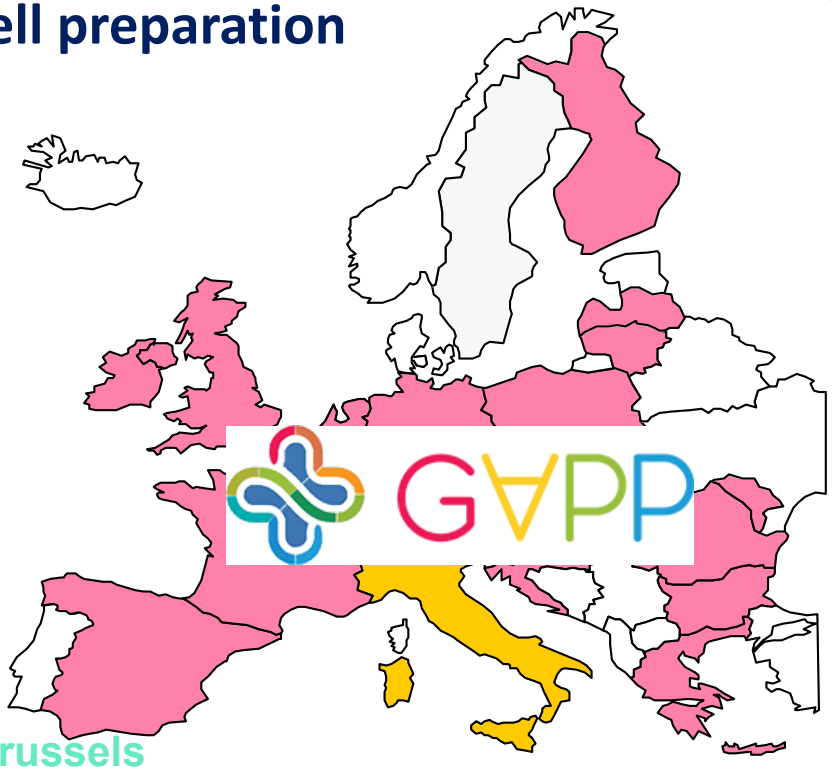
365 Core Team
March 2023

GAPP Joint Action 2018-2021

Co-funded by the Health Programme of the European Union

A large consortium of BTC Competent Authorities to define the **authorization pathways for tissue and cell preparation processes**

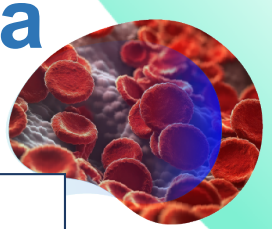
- **17 European Countries**
  - 16 EU MS
  - 1 non-EU MS
- **24 partners**
  - **1 coordinator**
  - **23** beneficiaries (+ 2 affiliated entities)
- **15 collaborating stakeholders**
  (NHSBT, SALAR, JPAC, Fundatia Renale, ESHRE, EBMT, ECDC, SOHO Consortium, ANSM, EFS, Hellenic National Blood Transfusion Centre, Croatian Institute for Transplantation and Biomedicine, Latvian State Agency of Medicine, EDQM, EHA)

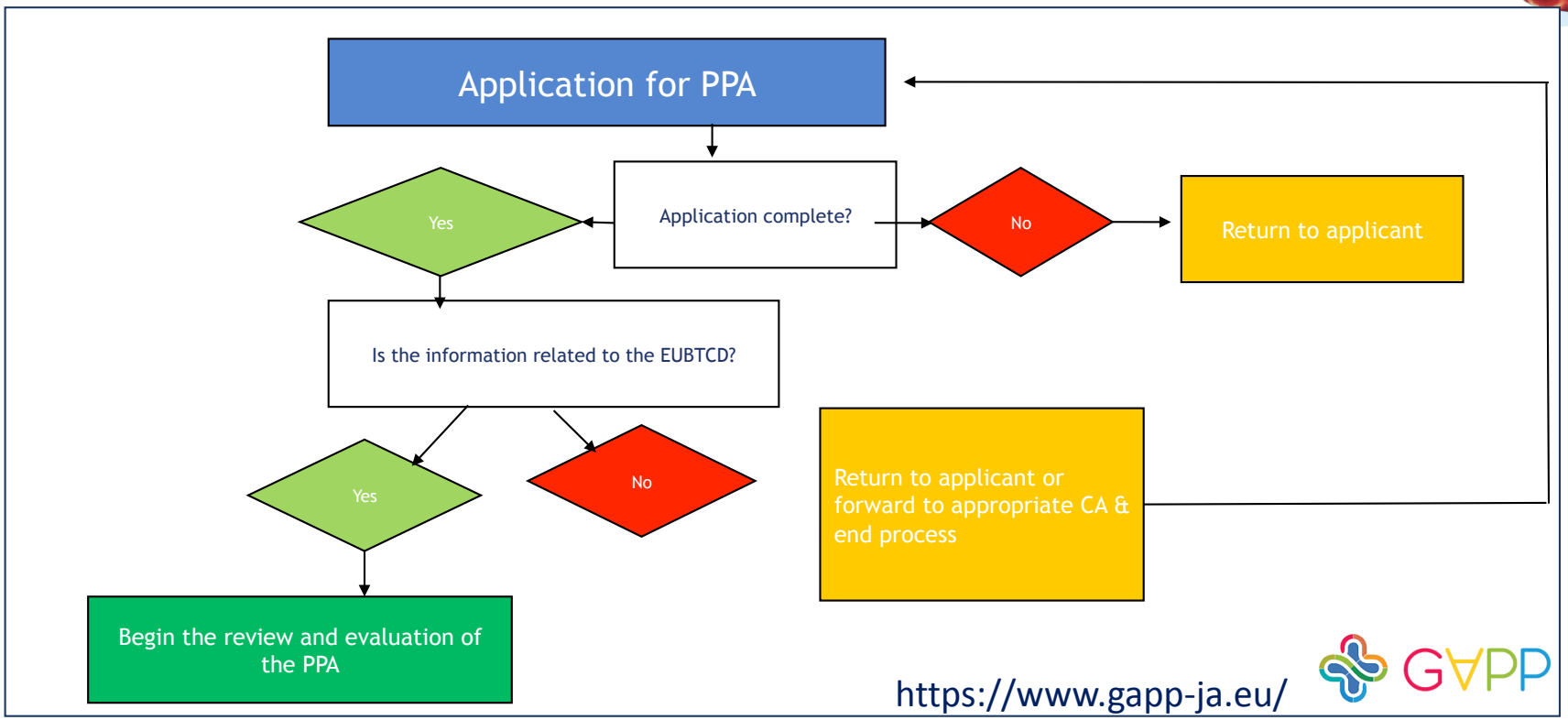


European Commission

SoHO CONFERENCE • 24 I 06 I 2024 Brussels

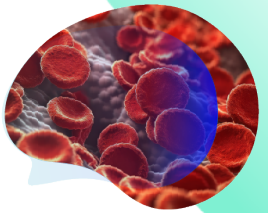
An application whenever a new SoHO or a change indicating novelty





The authorisation pathway for SoHO preparations

Consider relevant EDQM monographs



a) Systematic **Benefit/Risk Assessment** by the SoHO establishment, in order to determine the available evidence on safety, quality and effectiveness, possibly through EURO GTP tool

b) Submission of an **application**, including **laboratory validation** and other safety, quality and effectiveness data and, where relevant, a **clinical outcome monitoring plan** proportionate to risk

c) **Assessment** of the application by the competent authority

Grant authorisation for the SoHO preparation

OR

Grant an **approval of the Clinical Outcome Monitoring plan** or request an amended plan

OR

Refuse authorisation

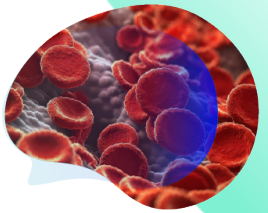
d) **Assessment** by the competent authority of evidence of safety, quality and effectiveness data gathered in clinical outcome monitoring

Grant authorisation

OR

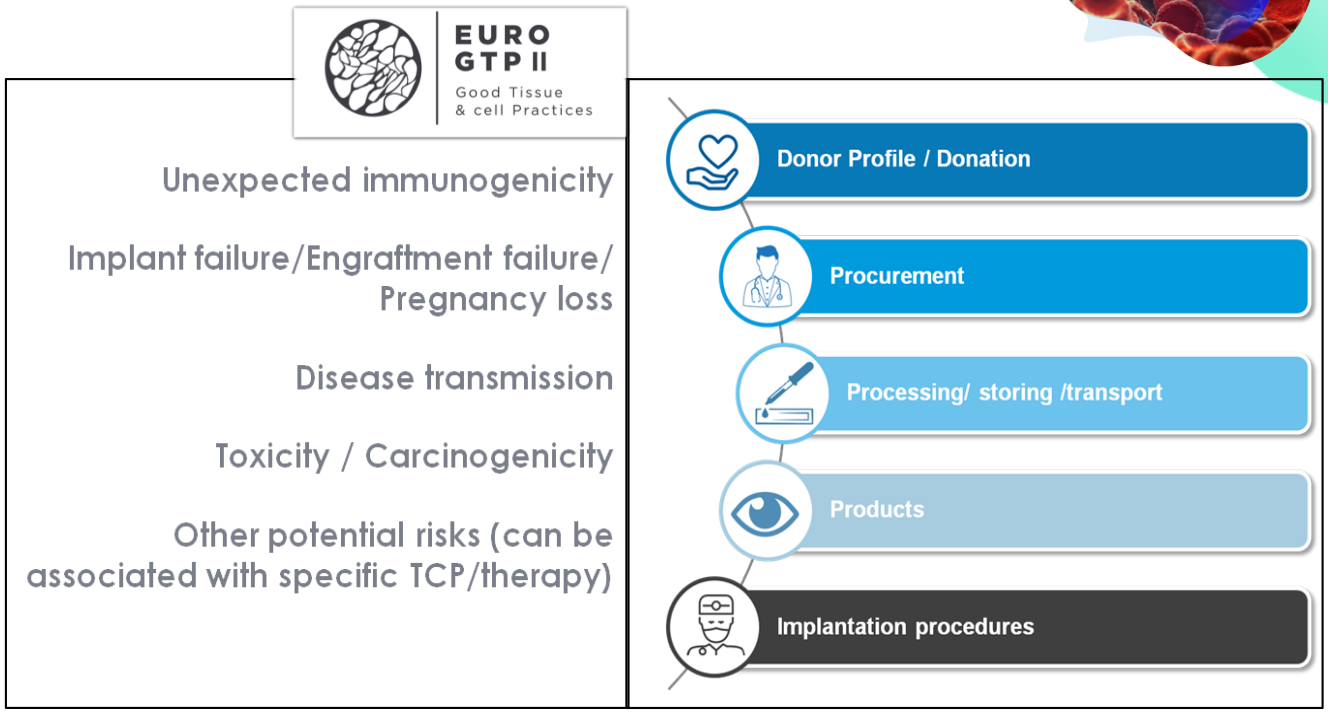
Refuse authorisation

Standard Risk assessment tool: EUROGTP II



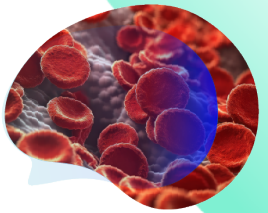
The **Euro GTP II** Methodologies [1] and Interactive Assessment Tool (IAT) [2] developed to assist professionals to:

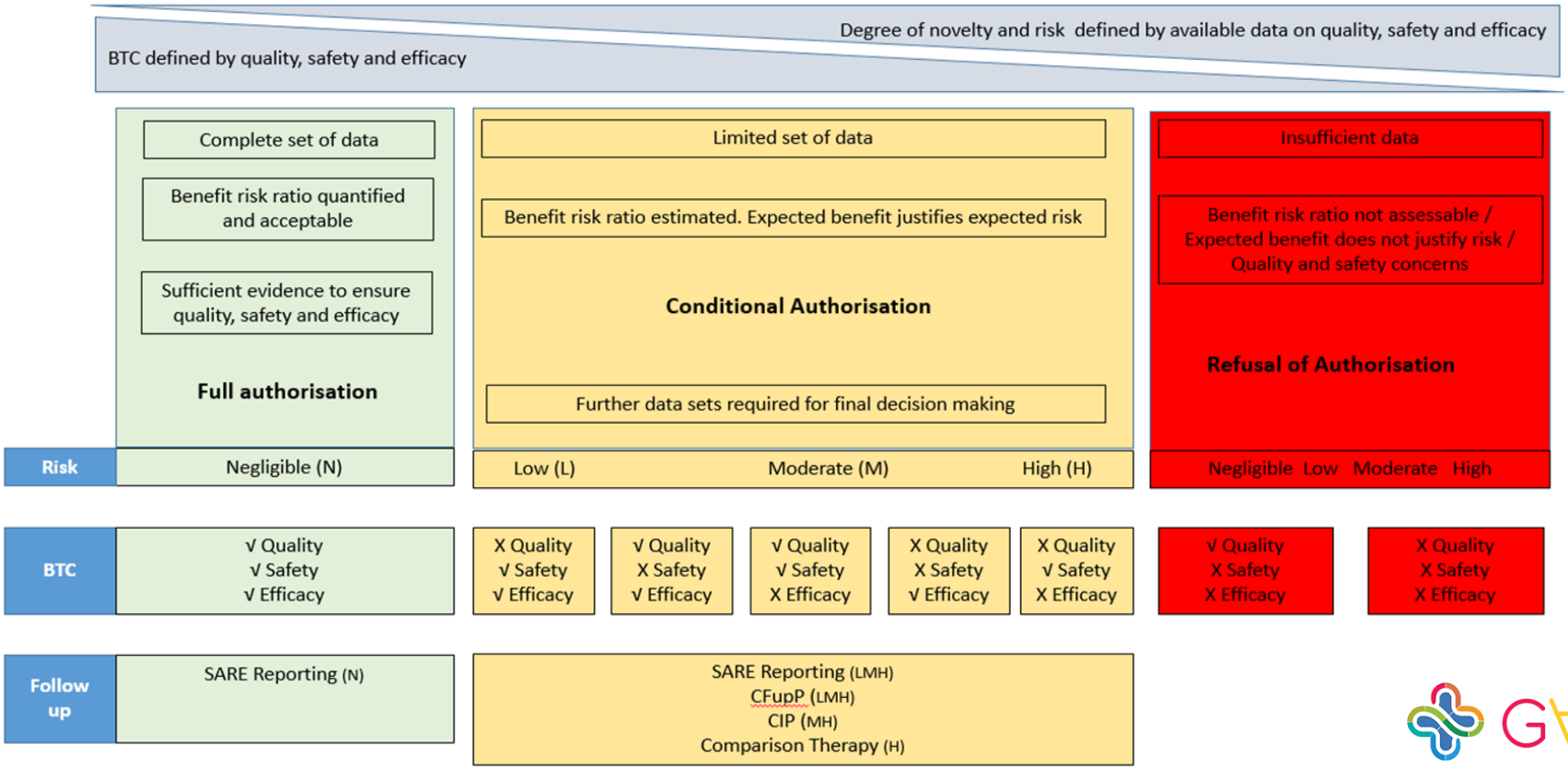
- Determine if a BTC or preparation process has any **novelty** (Step 1)
- Assess the **risks associated** with the BTC or preparation process (Step 2)
- Determine the extent of any **studies and/ or follow up required** to assure the safety and efficacy of BTC (Step 3)



(1) Details available on the website: https://tool.goodtissuepractices.site/
(2) Adopted by EDQM for implementation guidelines: https://soho-guides.edqm.eu/home

Risk/benefit balance





Clinical outcome monitoring in function of level of risks

Level of risk ➔

Possible use clinical trials/studies/low-intervention

Possible use Real World Data

GAPP-PRO will pilot and roll-out approach by 2027

14 Main beneficiaries

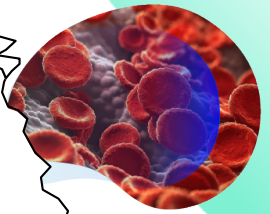
7 Affiliated entities

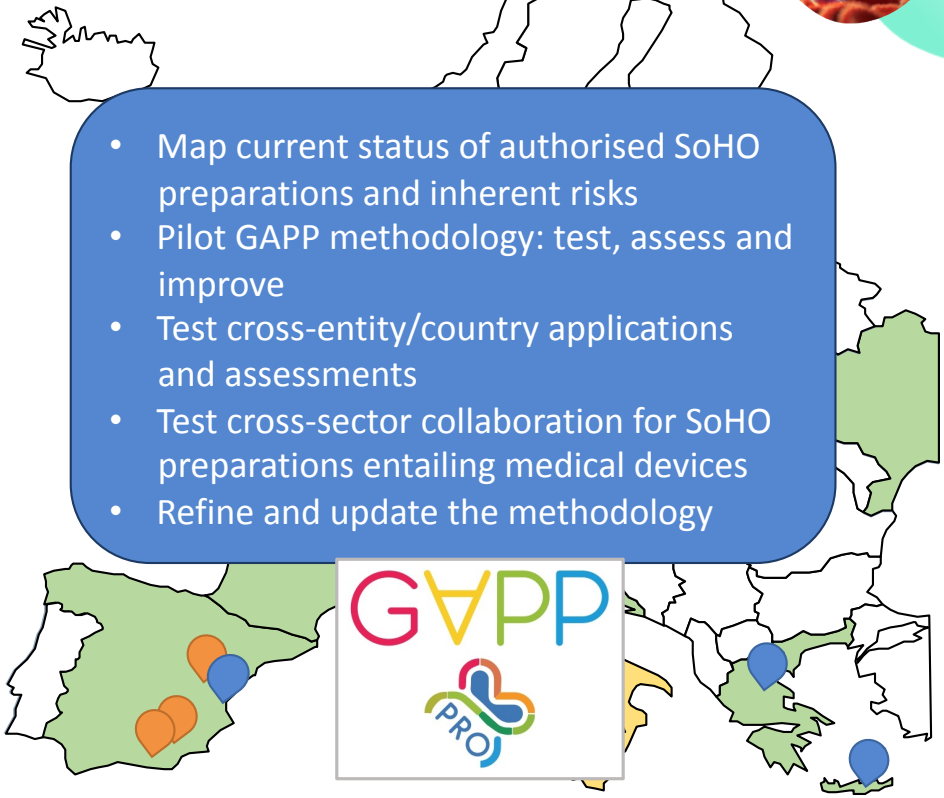
from 13 EU countries and 1 extra-EU country

Project start date: 15/02/2024

Project duration: 40 months (14/06/2027)

Co-funded by
the Health Programme
of the European Union





- Map current status of authorised SoHO preparations and inherent risks
- Pilot GAPP methodology: test, assess and improve
- Test cross-entity/country applications and assessments
- Test cross-sector collaboration for SoHO preparations entailing medical devices
- Refine and update the methodology

GAPP PRO