Kreuth V initiative: European consensus proposals for treatment of hemophilia using standard products, extended half-life coagulation factor concentrates and non-replacement therapies

Started in 1999

Experts from 15 European Community member states

4 meetings follow-up

WG1

- Access to prophylaxis for all patients
- Attainment of plasma factor trough levels of at least 3-5% when extended half-life FVIII and FIX products are used
- Treatment regimen personalization and choice of chromogenic assays for treatment monitoring
* Innovative therapies should be supervised by Hemophilia Comprehensive Care Centres

WG2

- Mandatory postmarketing data collection to assure the long-term safety and efficacy of new hemophilia therapies
- Establishment with adequate support under public control of national patient registries including the core data recommended by EMA and ISTH
- More collaboration to facilitate comprehensive data evaluation in Europe

WG3

- Clinical studies should be designed to provide the best possible evidence needed by regulatory authorities, HTA bodies and healthcare providers
- Discussed methodological aspects of hemophilia care in the context of access decisions particularly for innovative therapies

The dialogue between all stakeholders in hemophilia care and patient organizations should be fostered to implement these recommendation

Peyvandi *et al.*, Haematologica, 2020