

INTRODUCTION

Blood derived eye drops

- Sterile compounding + Biological raw material
- Autologous Serum (AS)
- Plasma Rich in Growth Factors (PRGF)

Indication & Mechanism

- Second-line therapy in the severe dry eye
- Growth factors and vitamins supplementation

CONTEXT

Requests from ophthalmologists of the UHC of Brest
→ Emergency nature for 2 patients

Limits of the subcontracting with the UHC of Rennes

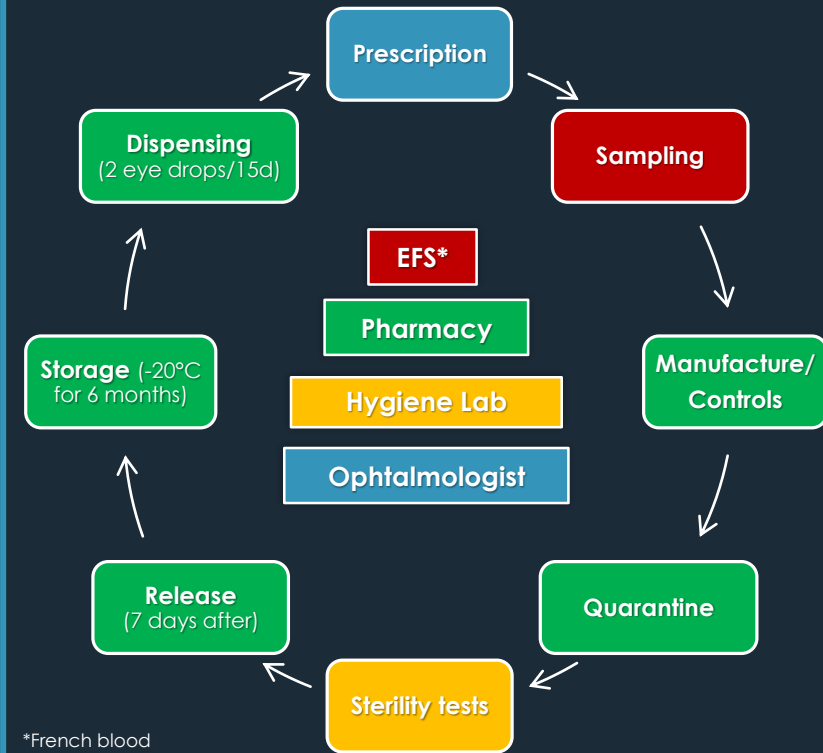
OBJECTIVE

Feasibility study and circuit development of the blood-derived eye drops preparation

CONCLUSION

Autologous serum eye drops preparation circuit established

→ Control and securing of a complex circuit by the pharmacy



MATERIAL & METHODS

- Literature review
- Consultation of medical devices (MD) suppliers
- Investigation of practices (circulated to 15 French production units)

- Incorporation of this activity with constant workforce
- Biological raw material handling (operator training ?)



RESULTS

Literature review

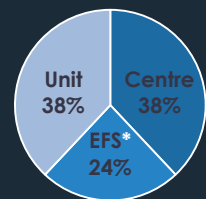
Clinical efficiency and therapeutic interest of the AS
PRGF/AS comparison in favour of the AS
→ **Selection of the autologous serum** as raw material
→ **Selection of a 20% dilution**

Consulted MD suppliers not selected

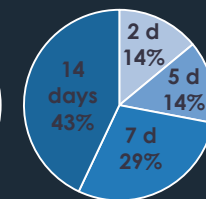
- MD aiming to secure and standardize the process
- Endoret® Kit** (Horus Pharma) : PRGF preparation kit
→ PRGF not selected
- Col® Kit** (Bexen Medical) : AS eye drops or other blood derivatives preparation kit
→ Lack of stability studies

Investigation of practices (7 answers)

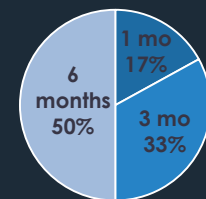
- Response rate : 47%**
- 100% are using the AS and a 20% dilution**
→ Confirmation of the results of the literature
- Disparity of the answers** throughout the preparation circuit → **lack of standardization**



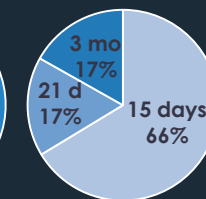
Sampling structure



Delays of the sterility tests release



Stability after freezing



Dispensing frequency

PERSPECTIVES

Establishment of an emergency circuit
→ **Various perspectives remaining to be dealt with**

- Media Fill Test** → process validation
- Professionals and patients support**
- Consulted MD** = future alternative ?
- Network constitution** for the provision of the AS eye drops