

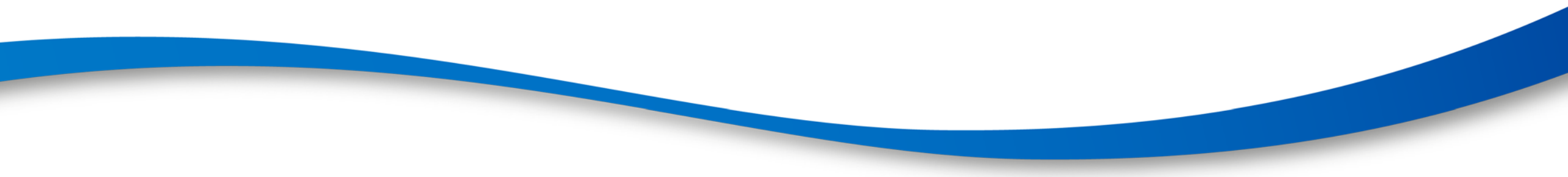
BBTS Annual  
Conference 2016

# Bringing tears to your eyes: Serum Eyedrops

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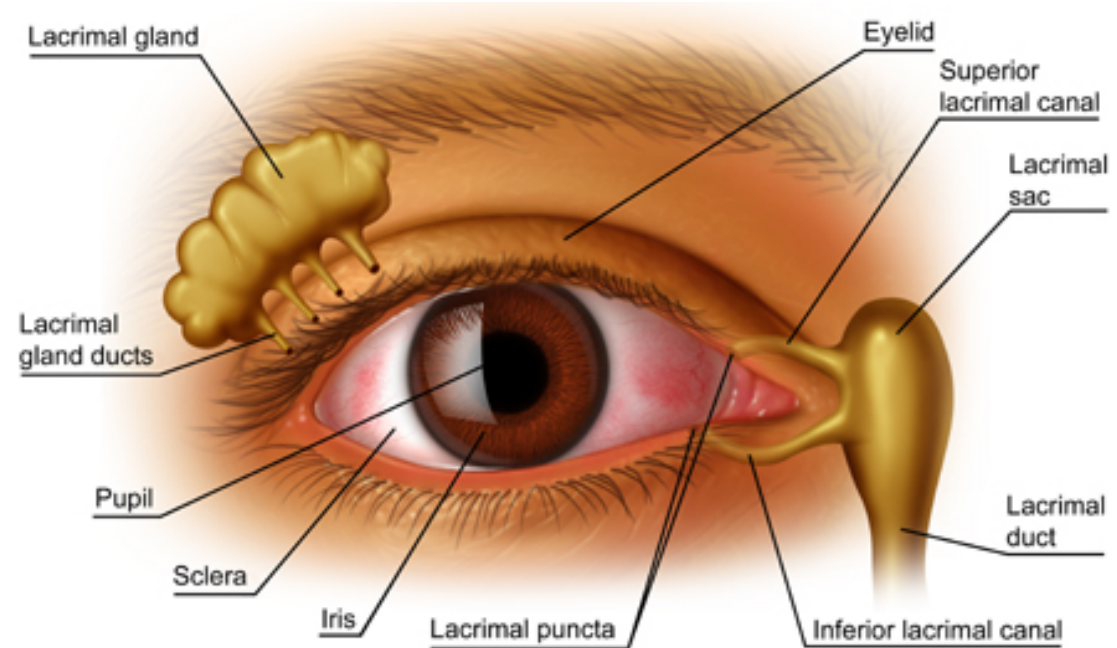


# Disclaimer

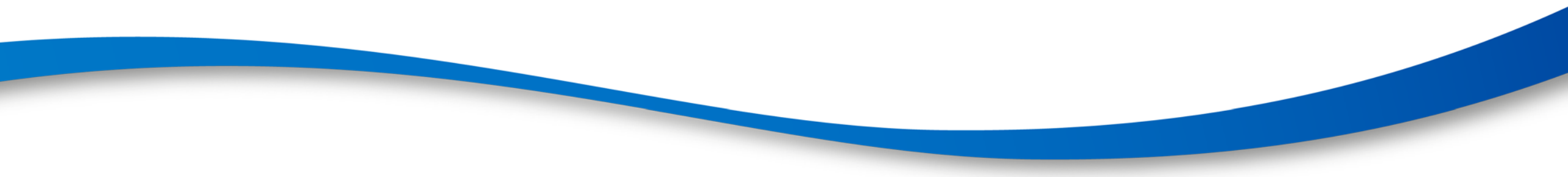
- This talk will focus on service provision by NHSBT
  - No claims made regarding effectiveness of the product
  - Regulatory requirement
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# Tears

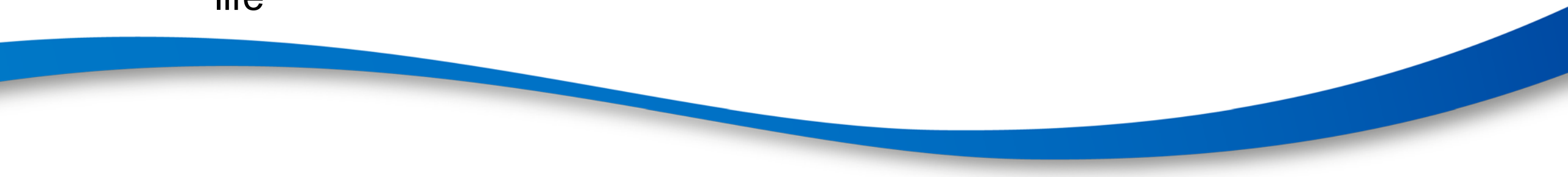
- We need tears to:
  - Lubricate the eyelids
  - Wash debris from the ocular surface
  - Deliver nutrients and growth factors to the cornea



# Dry Eye Syndrome(DES)

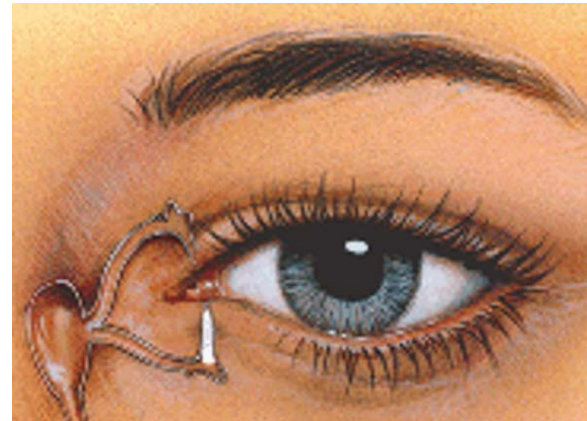
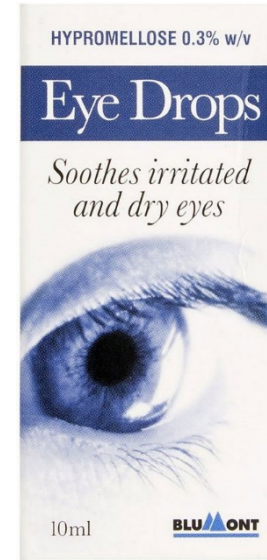
- Inability to form or maintain a normal tear film
  - May be caused by:
    - Autoimmune diseases (Sjogren's Syndrome, Stevens-Johnson Syndrome)
    - Other Immune related ( Graft vs Host disease)
    - Ocular injuries (e.g. chemical burns, post-laser eye surgery)
    - Side effects of disease or medication
    - Exposure Keratopathy: Abnormal eyelid function, causing difficulty in normal blinking, or fully closing the eyelids
    - Supportive ( following ocular surface reconstruction)
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# Effects of DES

- Mild cases:
    - Dry, 'gritty' sensation when blinking
    - Soreness
    - Irritation and red colouration
  - Severe cases
    - Extreme pain
    - Sensitivity to light
    - Eye infection
    - Loss of visual acuity
  - Severe cases of DES have a major effect on patient's quality of life
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# Treatment options for DES

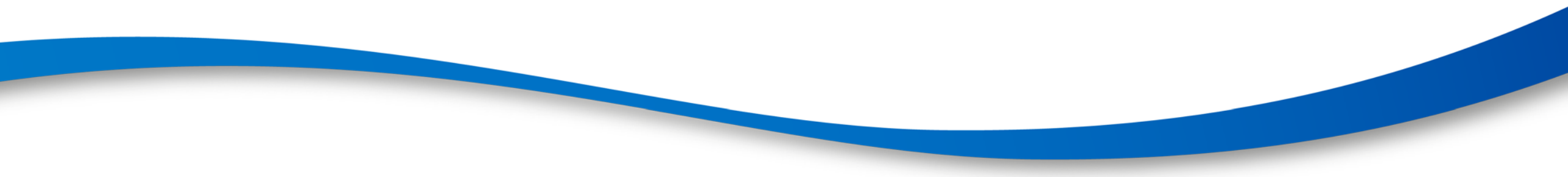
- Improve local environment; remove the source of the problem
- Use over the counter pharmaceutical eyedrops
- Surgical options; punctal occlusion
- If none of these work, serum eyedrops may be considered



# NHSBT Service – Origin!

- Derives from a controlled crossover trial comparing Autologous Serum Eyedrops (ASE) to conventional eyedrops –a study performed in 2002 by Dr Sheila MacLennan and ophthalmologists in Leeds\*
- Continued provision to trial patients; new patients referred through word of mouth
- Since 2003, NHSBT has provided a service for provision of autologous serum eyedrops to patients throughout the UK

Br J Ophthalmology \* 2004 May;88(5):647-52 (*open access publication*)



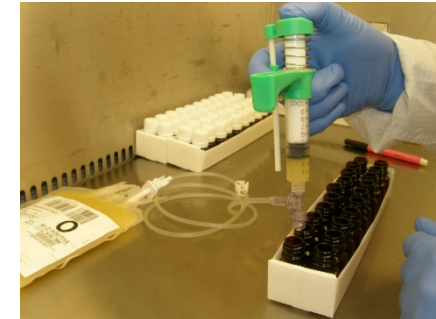
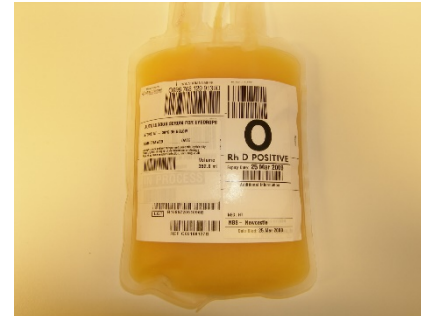
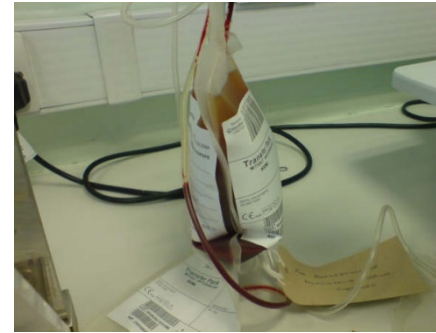
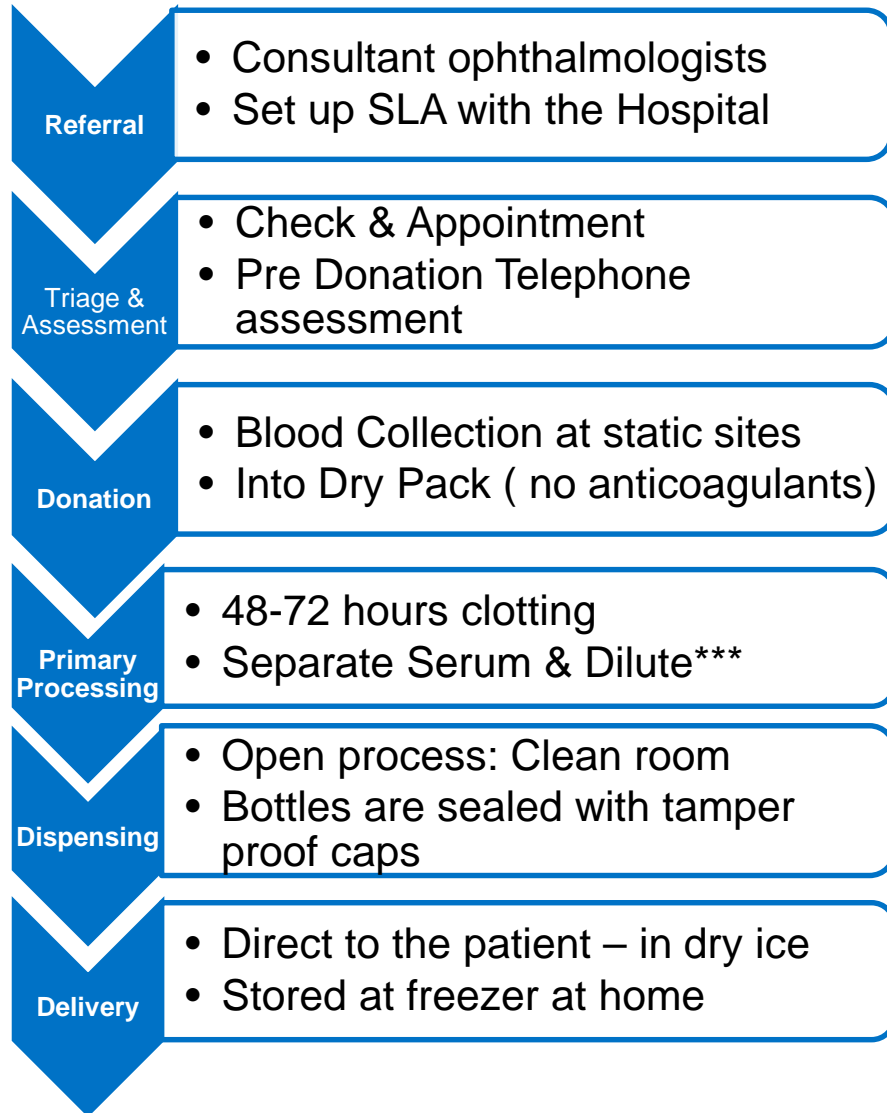


# ASE Service Development

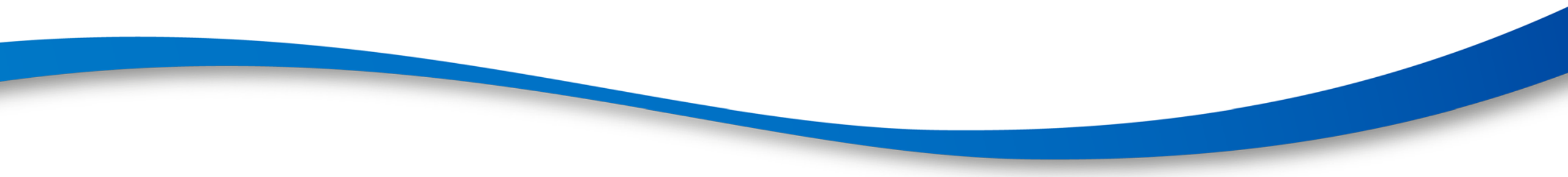
Year	Development
2002	A study performed by Dr Sheila MacLennan and Ophthalmologists in Leeds
2003	Continued provision to trial patients; Service established
2003-2006	<p>New patients referred through word of mouth, other centres – London, Newcastle, Oxford, Bristol, Liverpool</p> <p>Donations taken in Therapeutic Apheresis (TAS) units except London &amp; Newcastle</p> <p>Processing done at local blood centres</p> <p>Dispensing centralised where clean rooms were available initially in Leeds, then Sheffield, Bristol and Colindale before moving to Liverpool in 2006</p>
2013	Donation sites moved from TAS to BD static sites
2013	TS overall management responsibility - Central Administration Hub Processing centralised in Liverpool



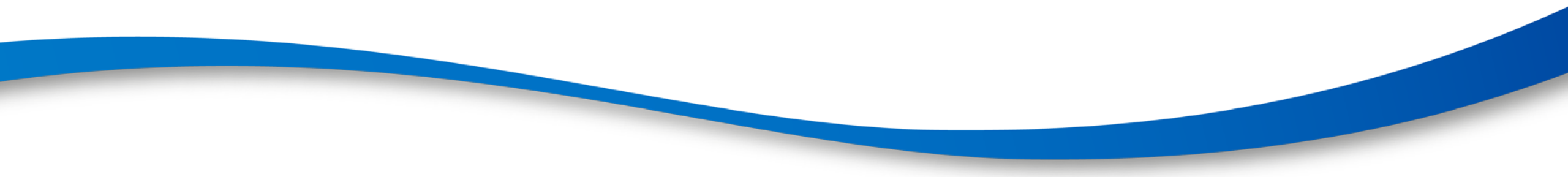
# How does the service work?



# Drivers for Change

- 50% patients are not healthy enough to donate enough of their own blood
  - Children cannot donate large amounts of blood
  - Patients in emergencies (need treatment ASAP) – in patients in hospital
  - CLINICAL NEED
- 

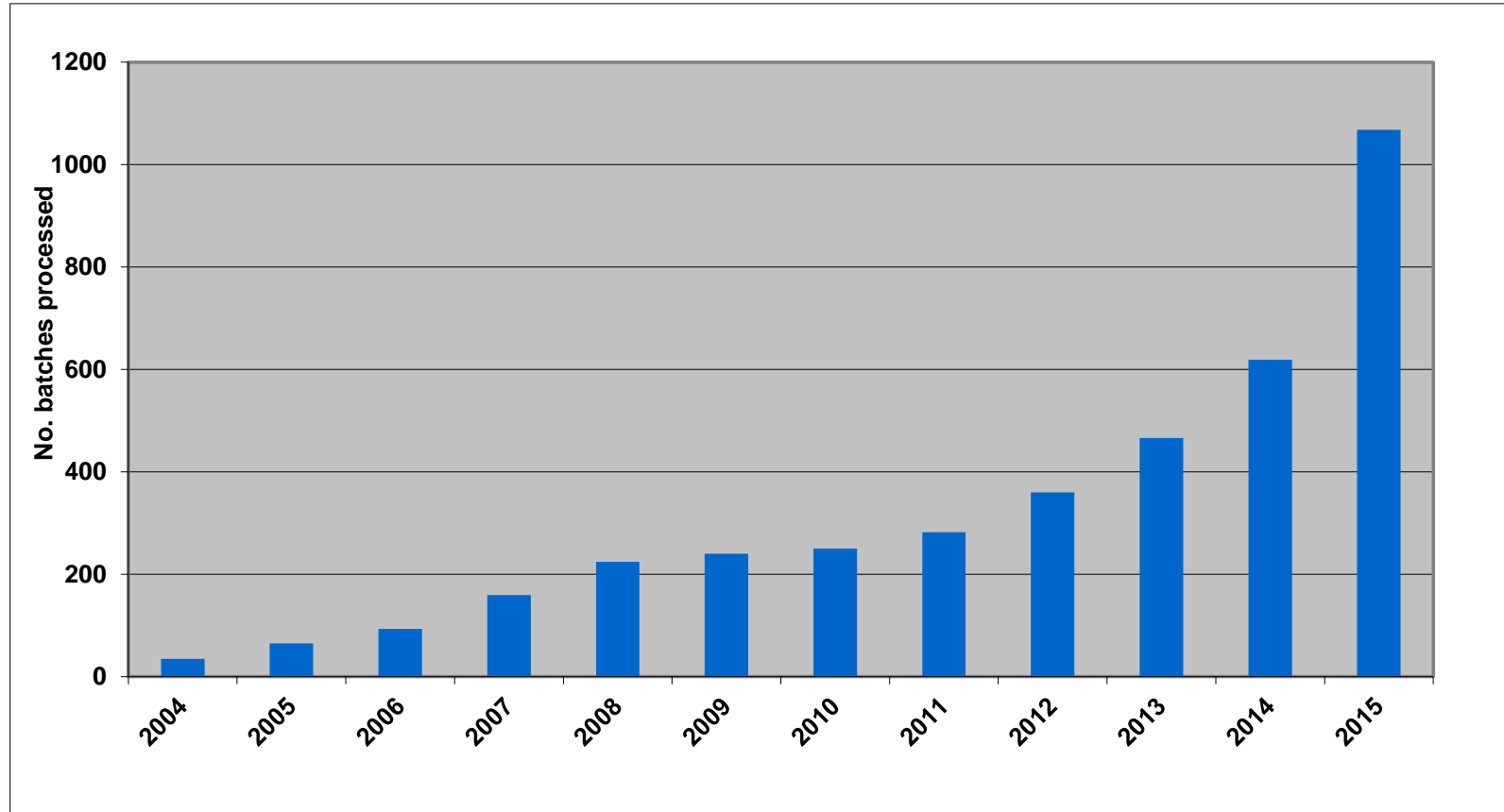
# Allogeneic Serum Eyedrops

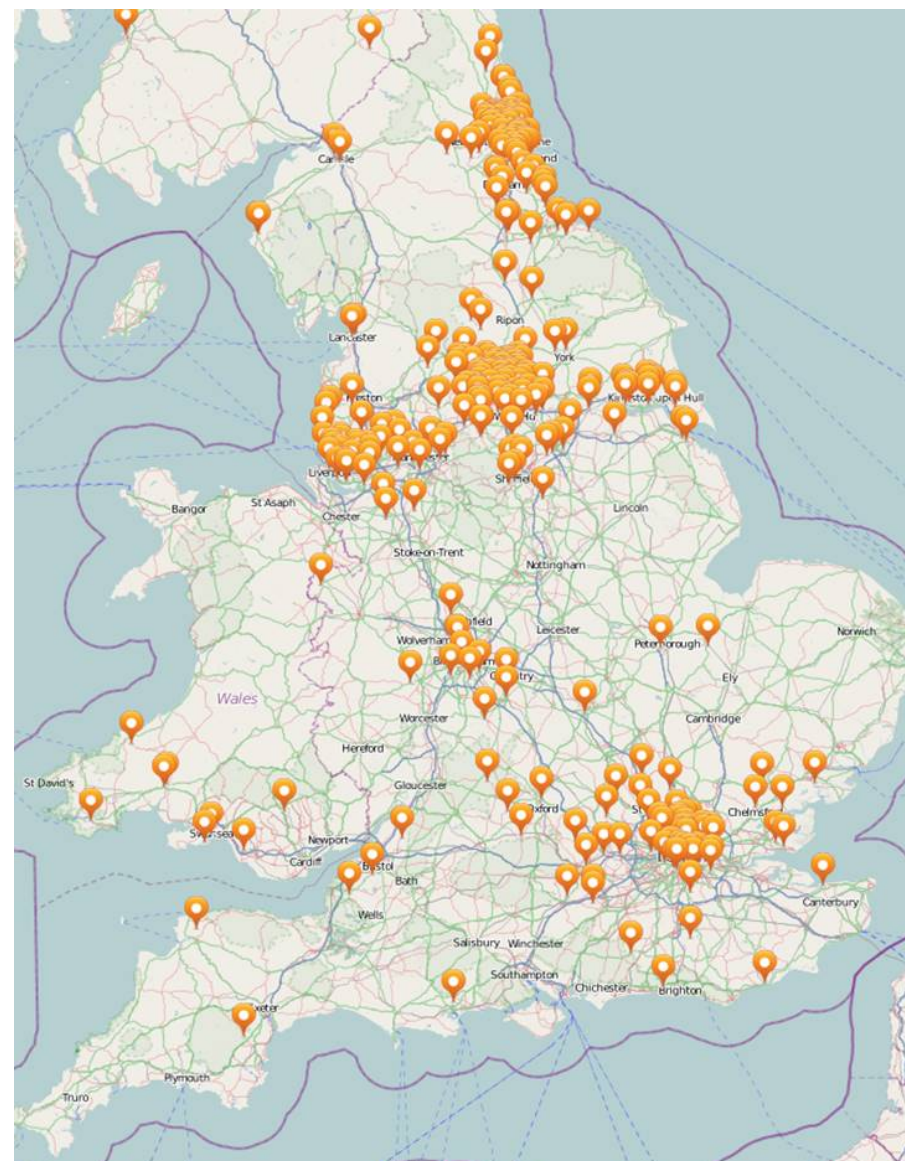
- Serum Eyedrops made from blood from volunteer donors
  - Male, and regular A or AB donors; currently collected in Liverpool and Manchester
  - June 2014 – Allogeneic Serum Eye drops introduced
- 



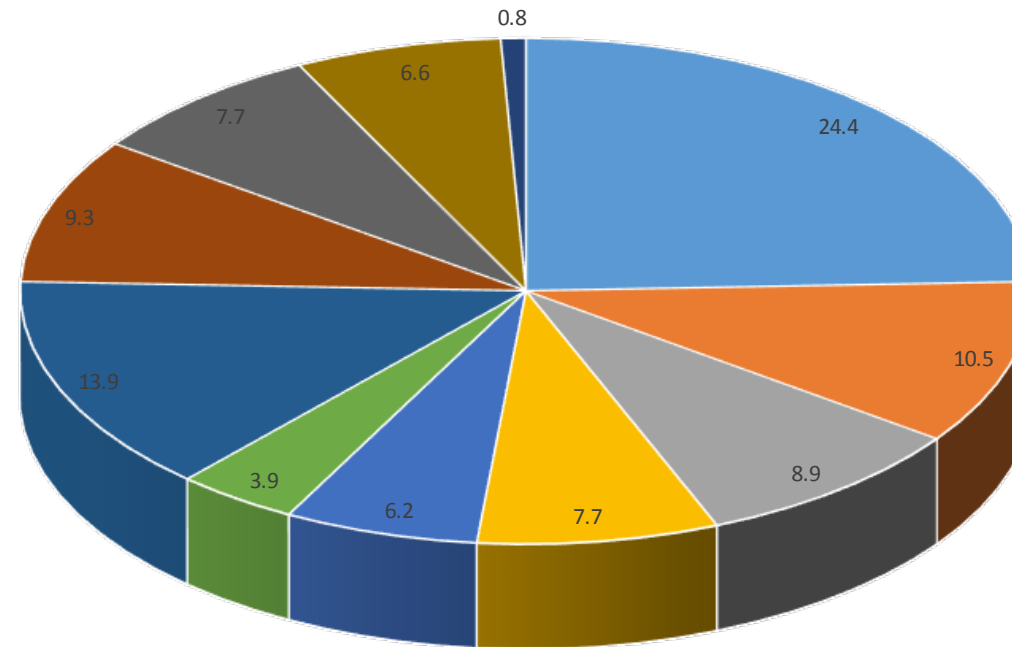
If patient is not medically suitable for blood donation,  
they have an option to receive AlloSE

# SE Activity





Medical Indication Resulting in Serum Eyedrop Referalls (%)

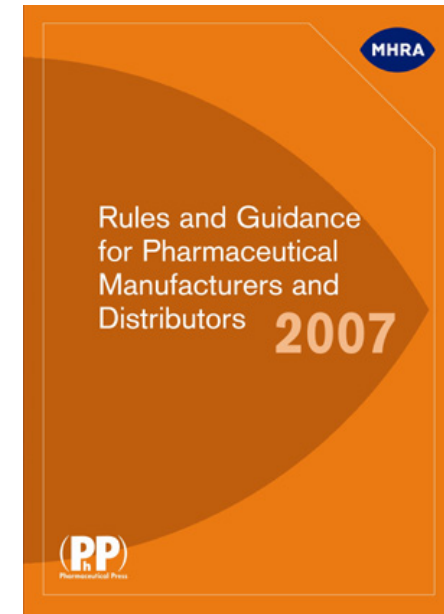


- Sjogrens related dry eye
- GVHD
- Ocular mucous membrane pemphigoid
- Steven's Johnson Syndrome/TEN
- Other immune related dry eye
- Non-immune dry eye
- Neurotrophic disease
- Injury/traume
- Supportive
- Inherited ocular surface disease
- Exposure keratopathy

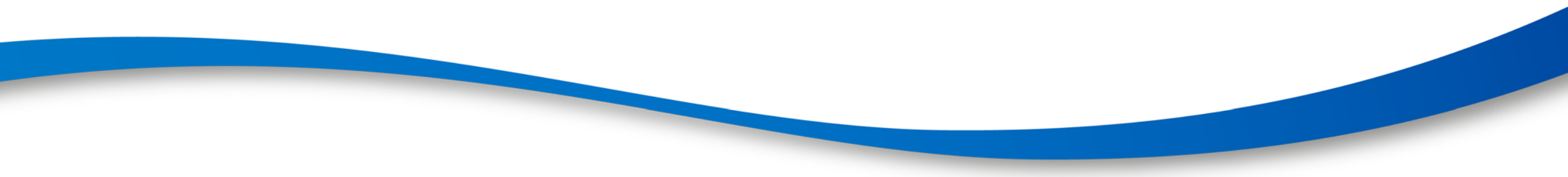


# Regulation

- Blood Collection and serum separation – Blood safety and Quality Regulation
- Serum Eyedrops are classed as an unlicensed ('special') medicine
- This requires that we hold a manufacturing license, issued and inspected by the MHRA
- Inspections at 2 yearly intervals
- Must be prescribed on a patient specific basis by a doctor
- The 'unlicensed' status of serum eyedrops severely restricts how the service can be promoted



# Standardised clinical follow up

- Standardised clinical follow up was introduced for all new patients
  - This collects clinical, and patient reported outcome measures
  - Currently, this is a paper based system, but a web-based collection system delayed
  - The objectives of this are to:
    - Collate data to inform RC Ophthalmologists guidelines
    - Possibility of NICE accreditation
    - will help with funding applications
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# Future



# Acknowledgement

- NHSBT Staff
- Hospital Staff
- Patients
- Donors

**CARING /EXPERT/QUALITY**

