

MediSieve

Our experience with NIHR i4i Connect Grant

16 October 2018

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www.medisieve.com

 @MediSieve

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***National Institute for
Health Research***

About MediSieve

2015-16:

- Company spun-out from University College London
- £350k of seed investment
- £200k grants (Wellcome Trust and Innovate UK)
- Clinical prototyping

2017:

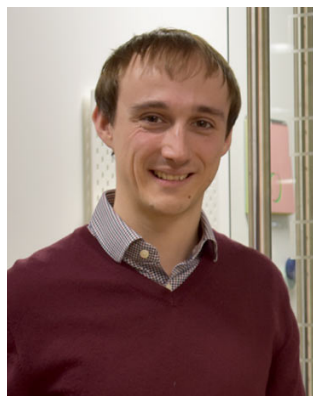
- Move into own facilities
- Start animal trials
- £200k of grants (NIHR & EU)

2018:

- £1.75M equity funding
- Completed animal trials
- First-in-man clinical trials (Q4)



About Us



George Frodsham
CEO



Cristina Blanco
Head of R&D



Chris Jones
Strategic Director



Will Twigger
Product Engineer



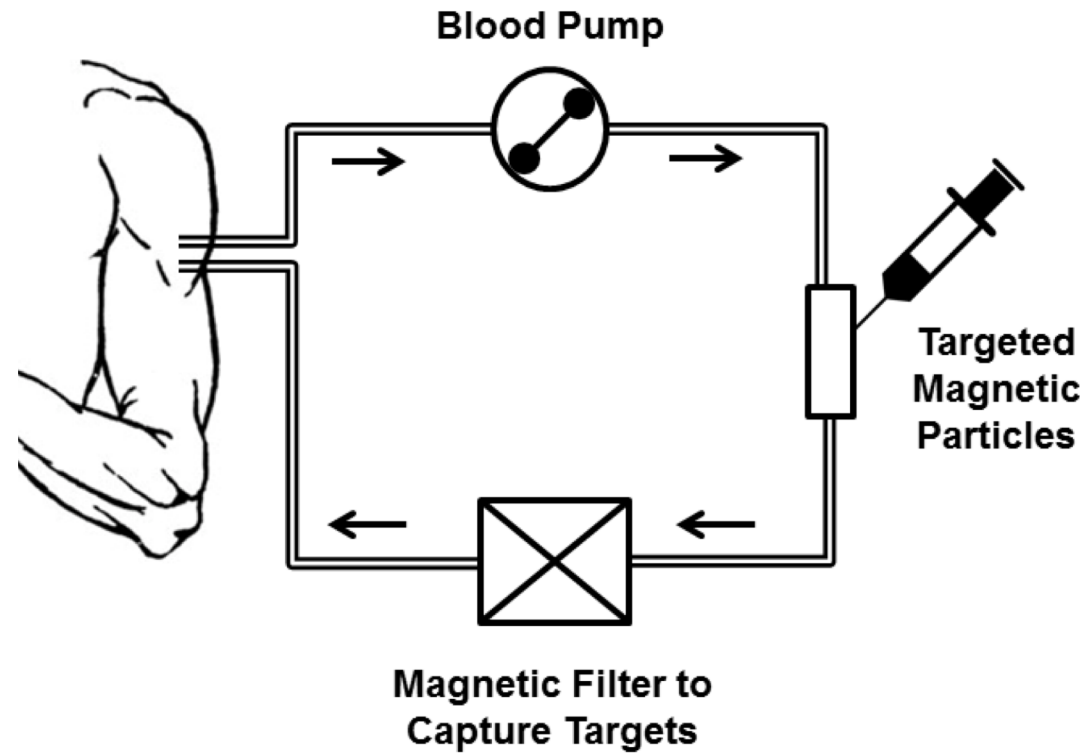
Alice Mazzer
Senior Biochemist



Lucy Moran
Biochemist



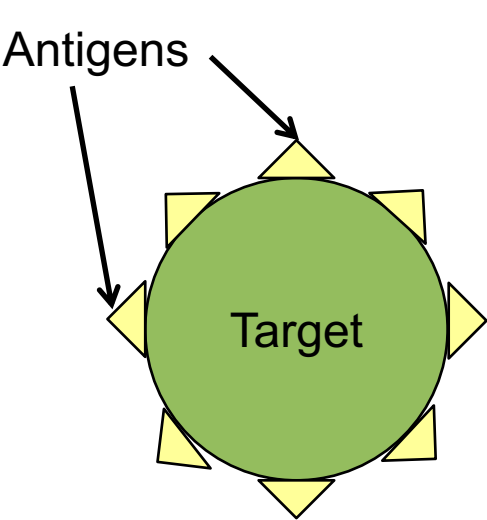
Quentin Pankhurst
Quality & Regulatory Director



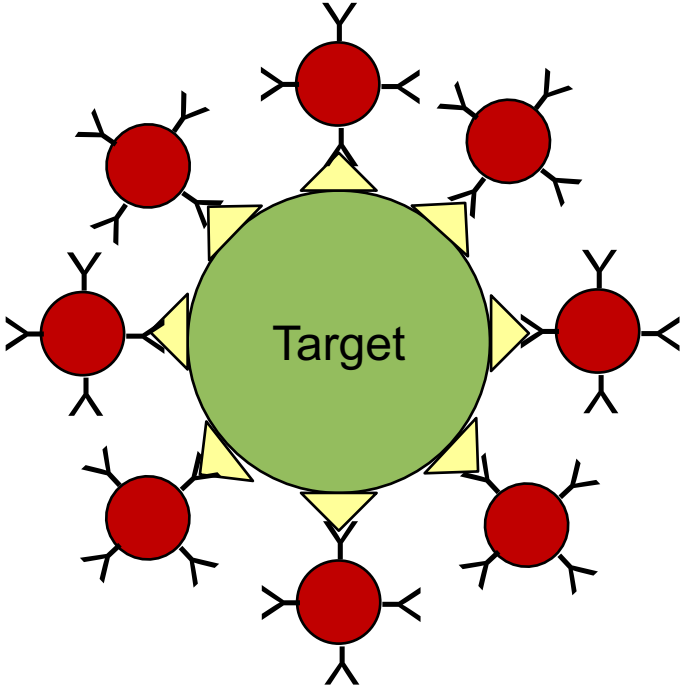
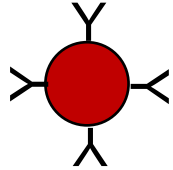
MAGNETIC BLOOD FILTRATION

Magnetic Labelling

Magnetic particle + Antibody = Targeted magnetic particle

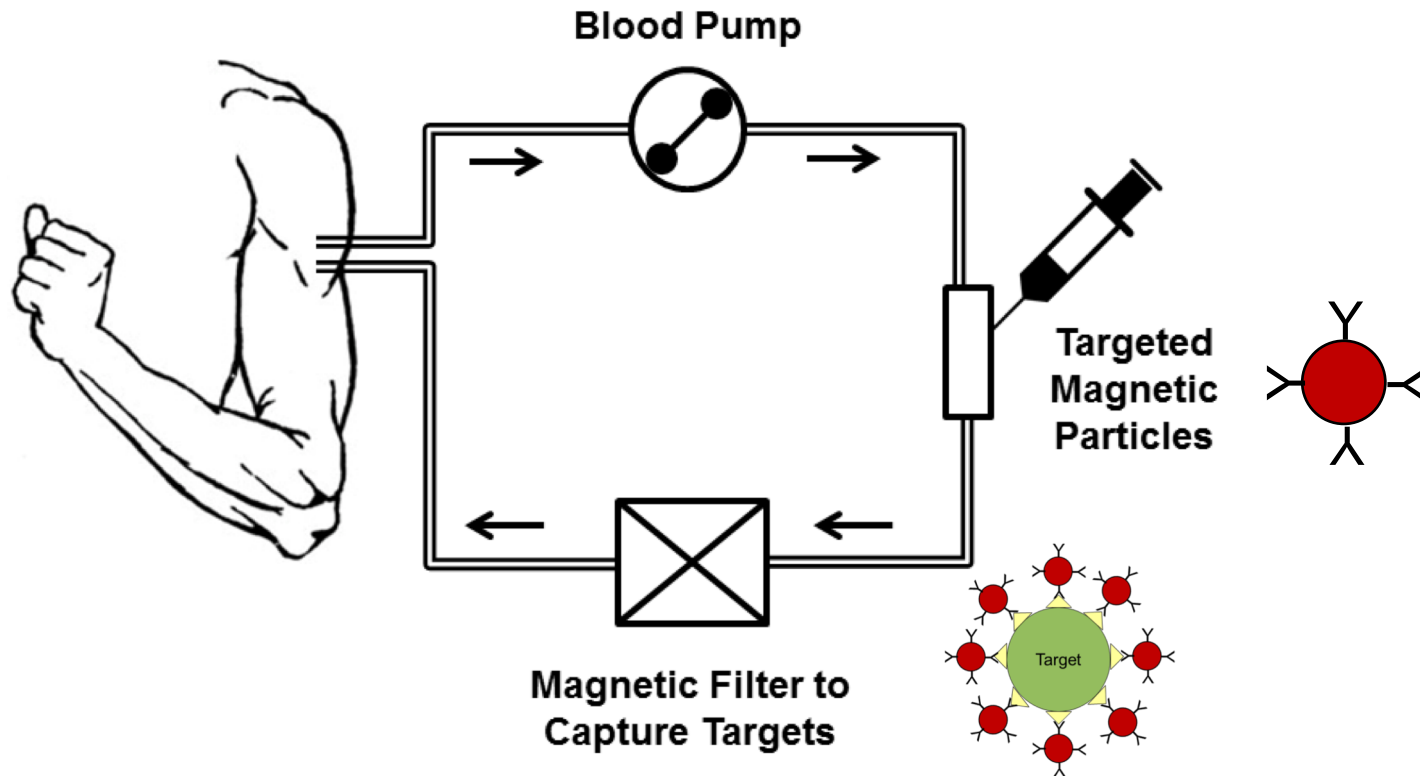


Y



Magnetically labelled target

Magnetic Blood Filtration



- ✓ One-off treatment for severe cases
- ✓ Treatment time 3-4hrs
- ✓ Treat any patient
- ✓ Cost-effective
- ✓ Integrates with standard hospital equipment

Anything that can be magnetically labelled can be removed

DE GRUYTER

Biomed. Eng.-Biomed. Tech. 2015; 60(5): 393–404

George Frodsham and Quentin A. Pankhurst*

Biomedical applications of high gradient magnetic separation: progress towards therapeutic haemofiltration

DOI 10.1515/bmt-2015-0056

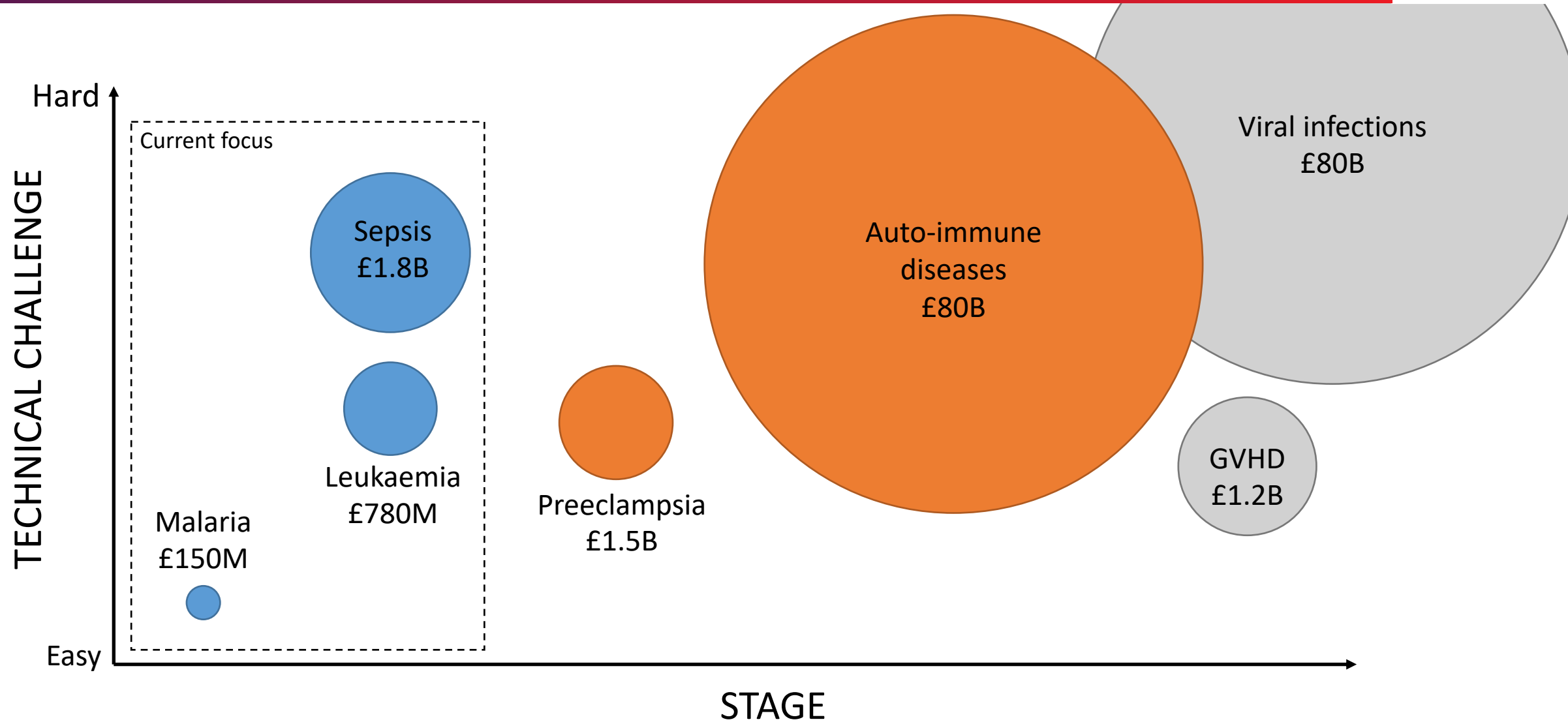
Received March 18, 2015; accepted September 8, 2015

Abstract: High gradient magnetic separation is a well-established technology in the mineral processing industry, and has been used for decades in the bioprocessing industry. Less well known is the increasing role that high gradient magnetic separation is playing in biomedical applications, for both diagnostic and therapeutic purposes. We review here the state of the art in this emerging field, with a focus on therapeutic haemofiltration, the key enabling technologies relating to the functionalisation of magnetic nanoparticles with target-specific binding agents, and the development of extra-corporeal circuits to enable the *in situ* filtering of human blood.

magnetic dipoles, this force is given by $F=(\mathbf{m}\cdot\nabla)\mathbf{B}$, where $\mathbf{B}=\mu_0(\mathbf{H}+\mathbf{M})$ is the magnetic flux density in the particle, μ_0 is the permeability of free space, and $\mathbf{M}=\mathbf{m}/V=\Delta\chi\mathbf{H}$ is the magnetisation of the particle, where $\Delta\chi$ is the difference in magnetic susceptibility between the particle and the surrounding medium (which in most cases is water) [80].

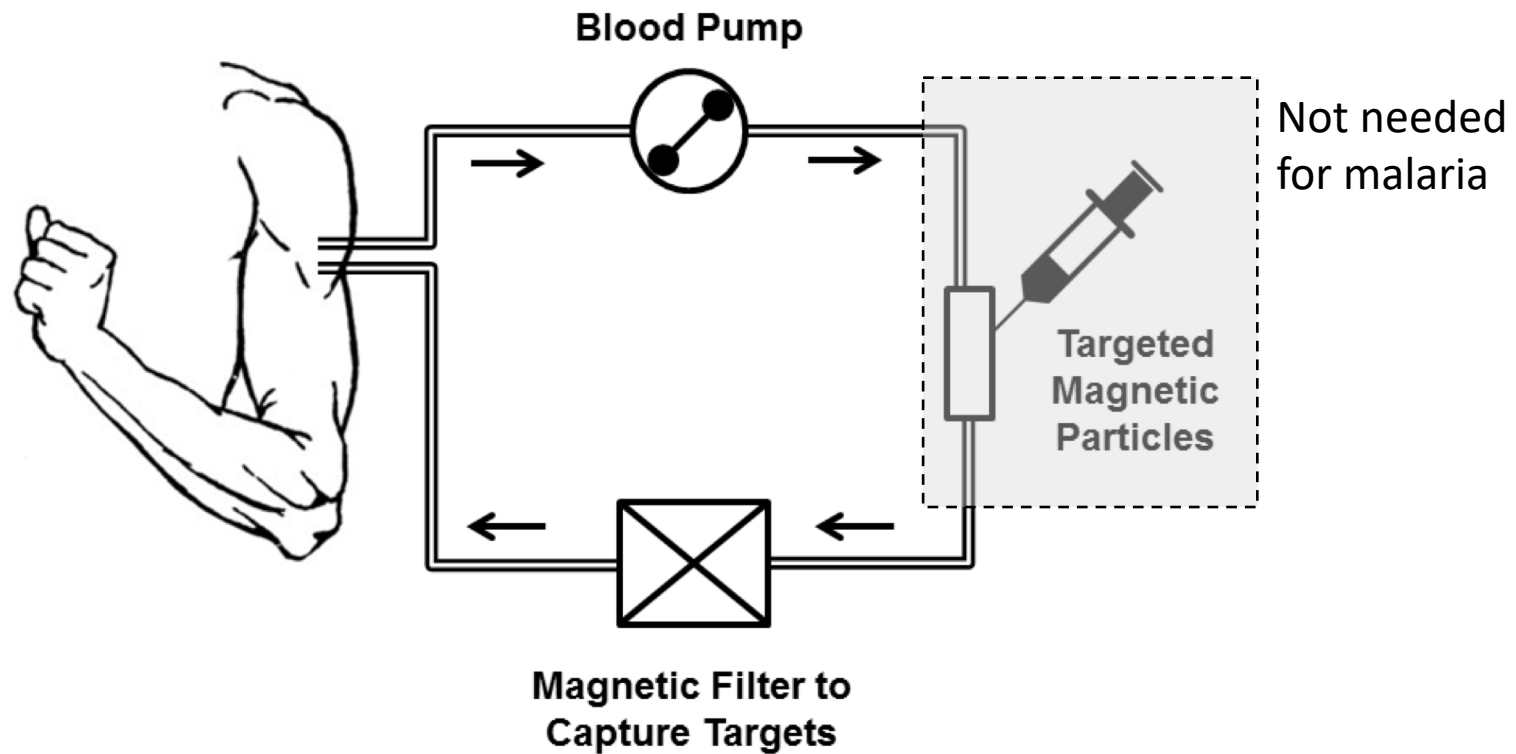
HGMS has a similarly long history of application in the bioprocessing industry, particularly in the field of protein purification [28, 31, 47, 70]. Here the approach is different, in that biochemically functionalised magnetic particles are added to the fermentation broth (or another such crude bioprocess fluid) to act as an adsorbent species that can then be conveniently separated out by passing the broth through an HGMS filter. This is known to be a highly efficient way to achieve the same sort of purifica-

Potential Applications



Why Malaria?

Infected cells are naturally magnetic



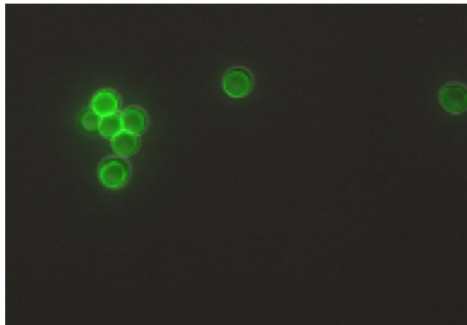
Products



MediSieve Magnet™
→ Same for each application



MediSieve Filter™
→ Same for each application



MediSieve Particles™
→ Different for each application

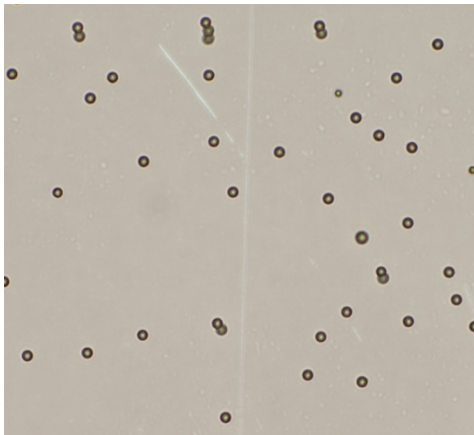
Tested in i4i project

Consumables – drive revenue



Filter & magnet:

- ✓ Class IIa medical device
- ✓ Passed ISO10993 biocompatibility testing



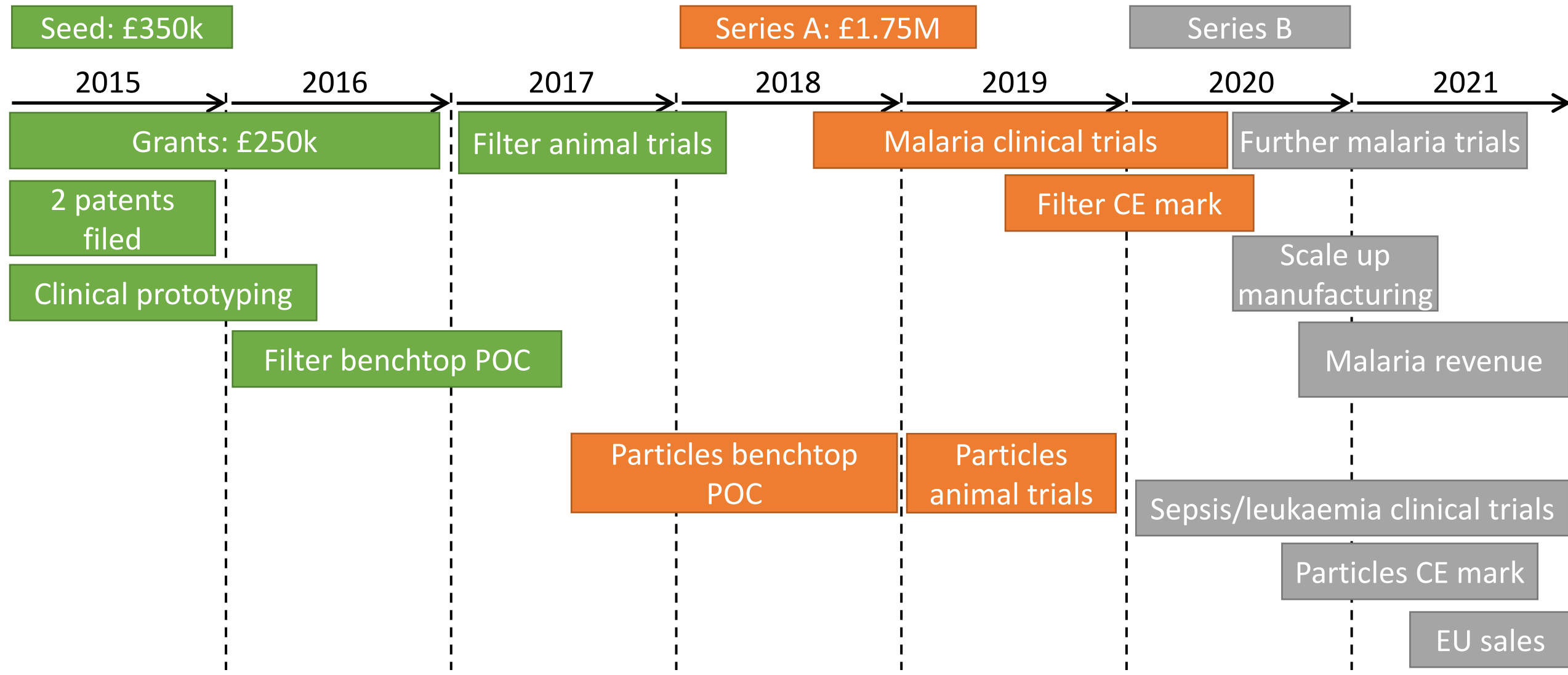
Magnetic particles:

- ✓ Class III medical device
- ✓ Extracorporeal only

- First CE mark, then FDA
- Regulatory consultants:
 - Medical Device Management (CE mark)
 - Isca Healthcare (MHRA approvals for trials)



Milestones



Aim: Perform first-in-man safety clinical trials of magnetic filter

Milestone 1: Finalise regulatory documentation for MHRA

Milestone 2: Make IRAS submission for approval to perform trials

Milestone 3: Clinical safety trial with n=10 health volunteers

Project duration: 12 months

Budget: £150,000

Challenges

1. Managing the “unknown unknowns”
2. Clinical trials site and partners
3. Scale of MHRA submission, even for simple trial
4. Managing timelines and costs

Magnetic Blood Filtration

- ✓ Platform technology with large potential market
 - ✓ First target: severe Malaria
- ✓ NIHR grant supporting first-in-man clinical trials

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