

Successful opening of the world's largest randomised controlled trial in organ donation

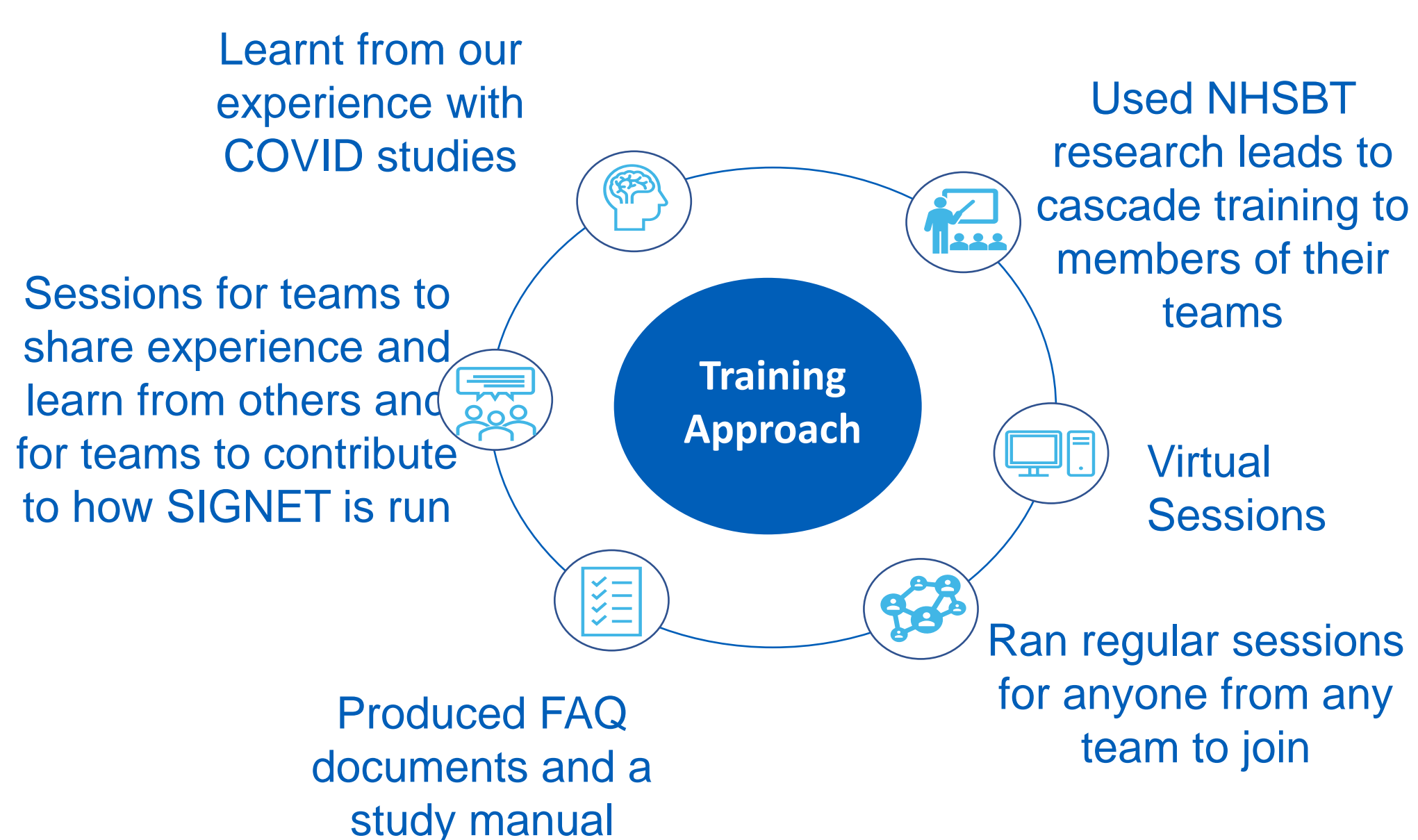
Dan Harvey, on behalf of SIGNET team in Clinical Trials Unit & OD Research Team

Background

- All organs removed from donors have already suffered a degree of damage
- Approximately 75% of hearts offered for transplantation are not utilised
- There is evidence that Simvastatin, a safe, affordable and commonly used drug, might limit the damage sustained by a donor heart before it is transplanted

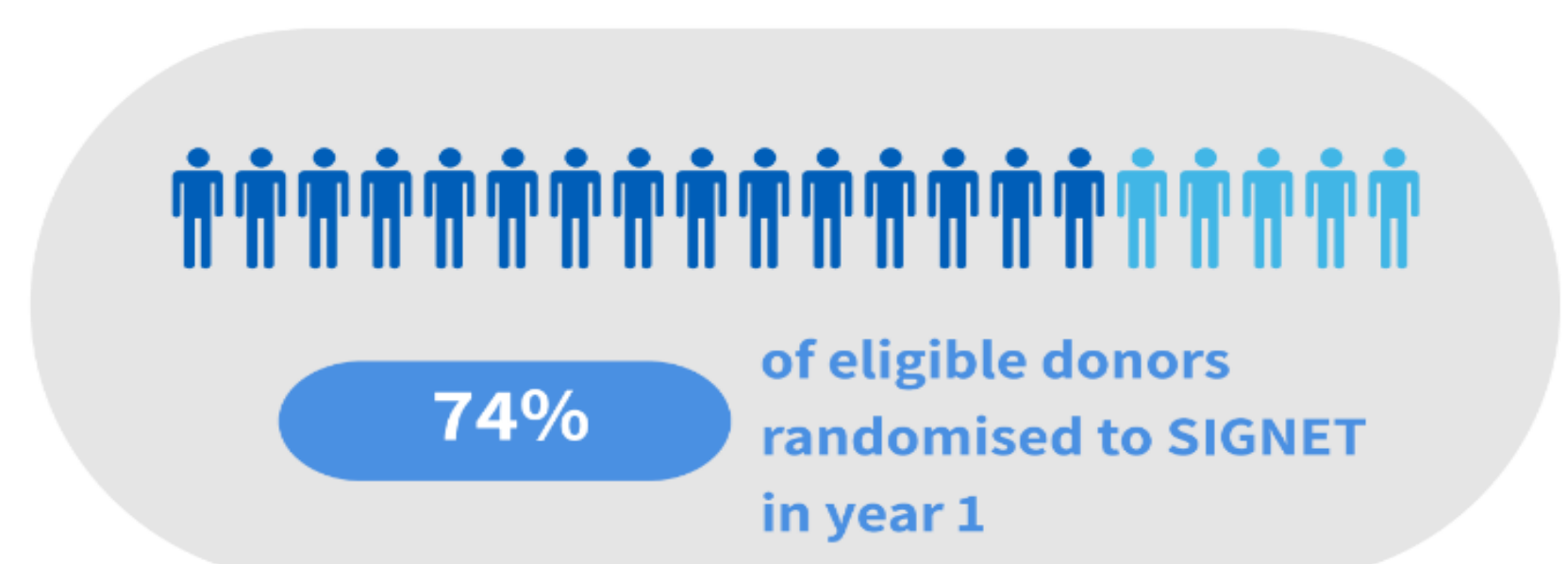
Methods

- SIGNET aims to evaluate the benefits of a single dose of Simvastatin given to potential DBD organ donors on outcomes in organ recipients
- It is a multi-centre, single-blind, prospective, group sequential, randomised controlled trial (RCT)
- 2600 donors will be recruited over 48 months, across level 1 and 2 and selected level 3 trusts nationally
- Study and site up summarised in diagram;



Results

- Over 500 people received training for SIGNET over a 4 month period
- In the first year of opening, 70 trusts (112 sites) opened to recruitment.
- **74% (320 / 435) of eligible donors randomised to SIGNET as at 13/09/2022.**



Discussion

- SIGNET is the largest global RCT in organ donation, benefitting from the unique strengths of the UK NHS infrastructure
- Utilising the SN-ODs' skills and knowledge of family approach and consent will enable us to reach a large recruitment target
- Rapid delivery of extensive training and site opening was achieved by offering self-booking onto regular centralised training sessions and regular communication between the NHSBT Clinical Trial Unit and study sites.
- Outcomes in organ recipients from randomised donors will be obtained from routinely collected data on the UK Transplant Registry, ensuring high data completeness

Conclusion

Embedding randomised controlled trials into usual organ donation pathways is feasible, acceptable and effective.