

The NIHR/RCS STEP Programme

Overview – What to expect

RCS/NIHR STEP

PILOT CASE STUDIES

SUMMARY



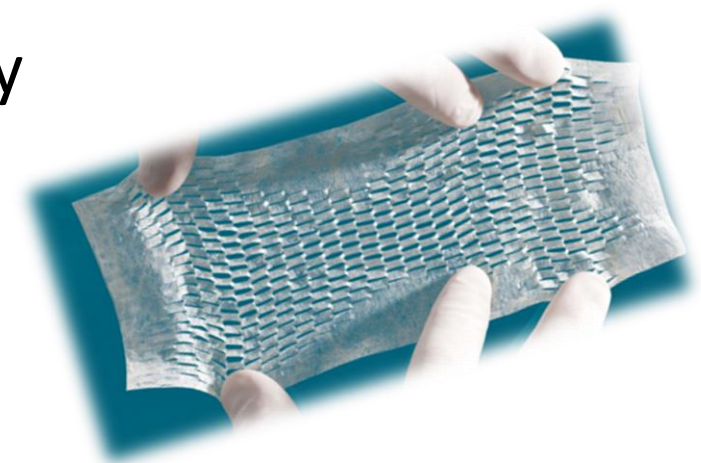
Royal College
of Surgeons
ADVANCING SURGICAL CARE

National Institute for
Health Research

SURGICAL TECHNOLOGY EVALUATION PORTAL

The 'Need'

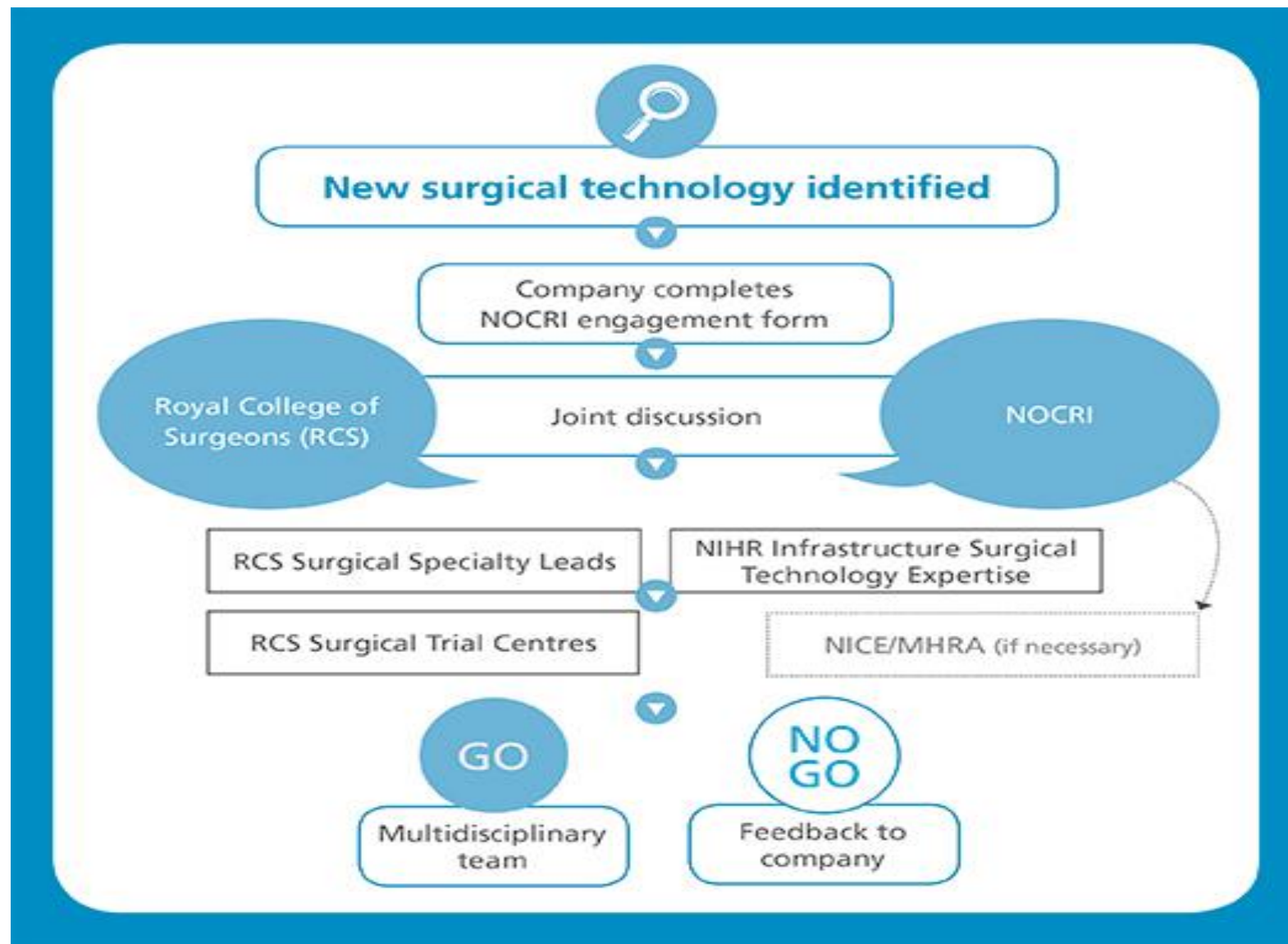
- Company enquiries in Surgical Technology
 - Implantables, Tools, ...
- Identifying relevant surgical expertise
 - Clinical study expertise, CTUs
- Multiple entry points for Industry
 - Confused landscape

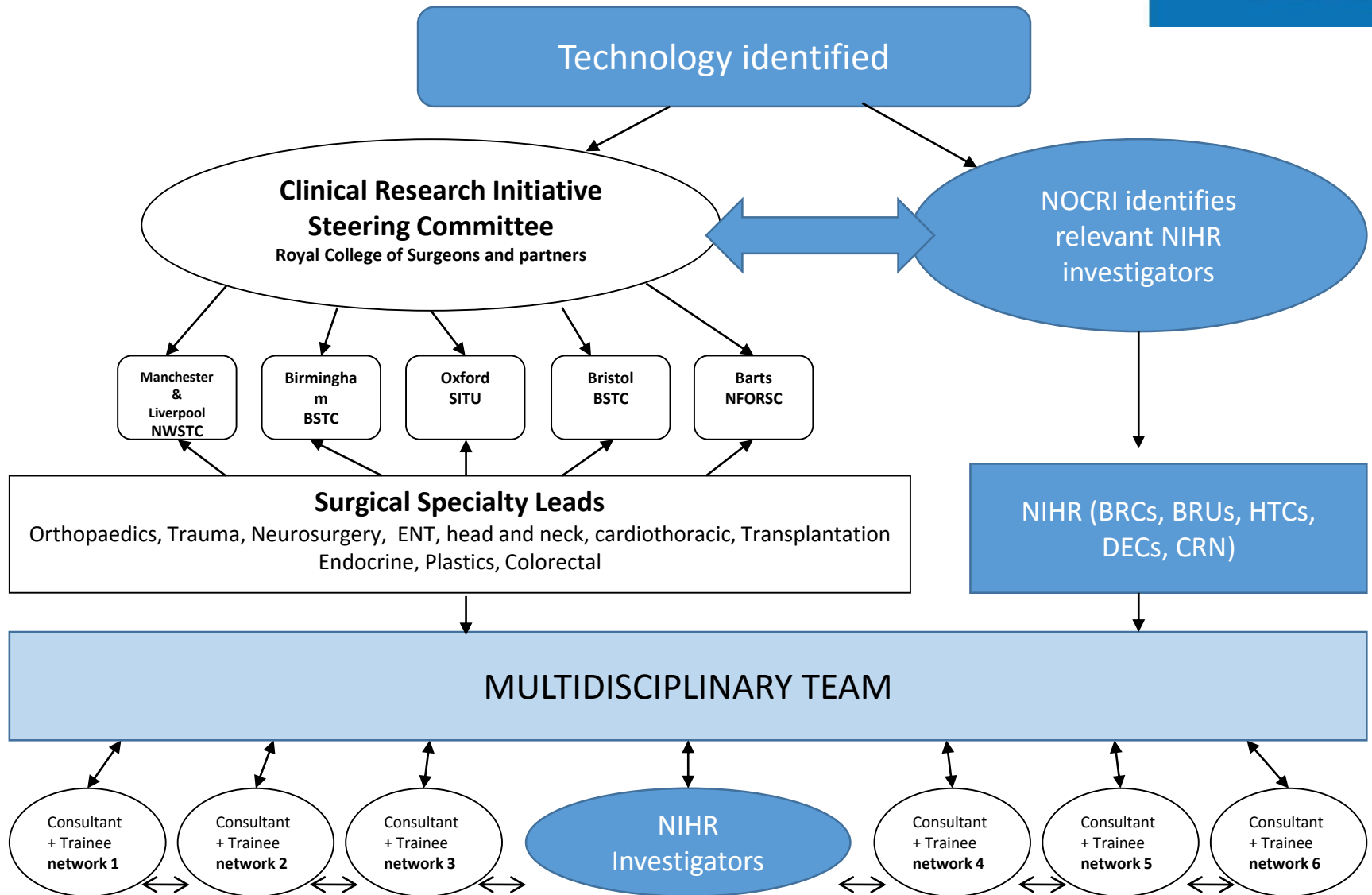


The 'Aims'

- Early feedback
 - 'Go'/'No Go' decisions
 - Reduced timelines
- Multidisciplinary team of experts
 - Surgeons, engineers, health economists, industry, ...

The 'STEP' Process





- In some cases the RCS surgical specialty leads and the NIHR investigators may be the same
- The idea is to cast a wide net to get feedback from as many experts as possible

STEP Pilot Case Studies

Company	Source	Date of initial meeting	Date Initial Engagement Form received	Initial Discussions with Experts	NIHR Infrastructure	RCS Infrastructure	Comments
1	Breast SSL (RCS)	2/7/15	2/7/15	7/10/15	NIHR CCF/NETSCC	King's	Funding sought for study
2	Leeds DEC	14/7/15	28/7/15	13/8/15	CRN		Study submitted (15/9/15)
3	NOCRI	3/9/15					No company contact after repeated follow up
4	Plastics SSL (RCS)	30/7/15	31/7/15	12/10/15	Woundtec HTC	Oxford	Feb 16 – Safety study agreed followed by a small pilot study
5	NOCRI	8/7/15	15/9/15	19/10/15	Leeds HTC	Leeds	Company drafting Study protocol with Leeds
6	RCS	9/11/15	18/11/15	To schedule	Trauma HTC	Oxford / Hull	No PIs identified to lead study
7	NOCRI	13/11/15	16/12/15	26/1/16	Trauma HTC	Oxford	Company have a follow up meeting with Trauma HTC
8	NOCRI	6/1/16	10/1/16	To schedule	Woundtec HTC	Birmingham	Connected company with experts

SUMMARY

- Clinical research infrastructure
 - NIHR& RCS
- STEP
 - Industry Need
 - Early 'Go/No Go' decisions
 - Multidisciplinary Teams
- Pilot case studies
- STEP formally launched
 - George Freeman on 18th May 2016

Thank you for your attention.

To work with the NIHR infrastructure contact the team at:

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NOCRI – SUPPORTING COLLABORATION

NOCRI industry engagement process

NOCRI provides industry partners with:

- **access to clinical expertise and capabilities at individual NIHR centres**
- **unique multi-centre collaborations in early technology design and clinical input enabling early phase clinical research in specific therapeutic areas.**

