

Improving the Environment for Medical Device Clinical Research

Stakeholder Workshop – 12 October 2009

Summary

The event was joint-badged by Association of British Healthcare Industries (ABHI), National Institute of Health Research (NIHR), Department of Business Innovation and Skills (BIS) and Health Technologies & Medicines Knowledge Transfer Network (HT&M KTN), and held on 12 October 2009 at the BIS Conference Centre. The audience was large, medium and small medical device manufacturers, NHS Innovation Hubs, Medilink and NIHR Clinical Research Network Industry Leads.

The programme was put together jointly by ABHI & DH, with input from NIHR Clinical Research Network Coordinating Centre and the HealthTech & Medicines Knowledge Transfer Network

The aims of the Workshop were to:

- To explore factors which could help the UK to be as good as the best in terms of a location for clinical investigations for multi-national MedTech businesses.
- Explain relative roles and ways of working of the NIHR Clinical Research Network and other intermediaries (Medilinks, Innovation Hubs)
- Map needs and capability in the Comprehensive Local Research Networks to address them
- Examine the issues surrounding questions and methodologies of MedTech investigations
- Provide a meeting point for an, as yet, unformed clinical research community in the MedTech industry.

Registered attendance at the meeting exceeded the capacity of 100. This was made up primarily of:

- Industry (41%)
- Support organisations (15%)
- Academics (14%)
- NHS (13%).

The following presentations were made (see separate Appendix B):

- NIHR's Role (Dr Louise Wood, Department of Health)
- Industry view of the NHS clinical research environment (Dr Kieron Day, St Jude Medical)
- The impact of NICE's evaluation of innovative medtech products on the development of clinical evidence (Mirella Marlow, NICE)
- **The role of business support networks: KTN and MedilinkUK** (Sue Dunkerton, KTN)
- **Improving UK Competitiveness in Med Tech Clinical Studies - A Perspective from the NHS Innovations Hubs** (Dr David Gleaves, MidTECH NHS Innovations West Midlands)
- The NIHR Clinical Research Network support (Dr Clare Morgan, NIHR).

There were two breakout sessions which discussed "Research Process Issues" and "Where are the gaps and how can we fill them?" Key messages from the different Breakout Groups (Appendix C) were reported

back to the whole audience (organisation given in Appendix D) The feedback from the breakouts was also captured in detail (see Appendix E) for use to inform decisions on priority areas for improvement in future.

Some of the main points were as follows:

- **Session 1: “Research Process Issues”:** Lack of awareness of improvements in the clinical research environment; there needs to be a map of what is available and people to guide one through it; industry needs better ways to find the right people to work with; everyone needs to get better at designing research projects appropriate to MedTech; maintaining/improving transparency of costs and processes; and vitally, the need to establish a community of MedTech research expertise.
- **Session 2: “Where are the gaps and how can we fill them?”:** How to do registries and other non standard studies cost effectively; Need to be aware of and address global research questions; Issues relating to data protection competencies in research sites; Getting research designed to meet user questions, not sales objectives.

Conclusions drawn at the end of the meeting were that:

- A number of the issues that were raised were already being addressed, with a number of the activities being described in the day’s presentations. These are summarised in Appendix A. Broad awareness of them, however, was limited.
- Stakeholder groups need to be aware of and review the outstanding issues raised
- The issues will be submitted to the NIHR Medical Devices Clinical Research Working Group for considering within its Communications Strategy, and prioritisation and action as appropriate
- Community forming activities will be pursued: these include the launch by the KTN of a Clinical Studies Special Interest Group; and the setting up of national and/or regional communities which is also being reviewed as part of the SME competitiveness programme under the HITF Strategic Implementation Report of 2007.

Appendix A

Summary of key activities and websites for sources of further information

Main Point	Activity	More information
Lack of awareness of improvements in the clinical research environment	IRAS NRES mCIA Confidentiality agreements NIHR Clinical Research Network <ul style="list-style-type: none"> • NIHR Costing Template • NIHR Co-ordinated System for gaining NHS Approvals • NIHR research support services Monthly Metrics on NIHR CRN Adopted Commercial Studies	www.myresearchproject.org.uk http://www.nres.npsa.nhs.uk/search/?q=medical+devices http://www.nihr.ac.uk/industry/Pages/industry_model_clinical_trials_agreement.aspx http://www.crncc.nihr.ac.uk/index/industry/collaborations.html http://www.crncc.nihr.ac.uk/index/industry/collaborations.html http://www.crncc.nihr.ac.uk/index/industry/costing.html http://www.ukcrn.org.uk/index/clinical/csp.html http://www.nihr.ac.uk/systems/Pages/systems_governance_advice_and_et_hics_systems.aspx http://www.crncc.nihr.ac.uk/index/industry/metrics.html
Map needed of what is	Innovation Landscape Stakeholders	http://www.nice.org.uk/about/nice/whatwedo/aboutmedicaltechnologies/

<p>available and people to guide one through it</p>	<p>KTN Funding Map</p> <p>NIHR Working with industry MediLinkUK Innovation Hubs NIC website NIHR CRN CC website: NOCRI</p>	<p>medicaltechnologiesprogramme.jsp?domedia=1&mid=74C0ED99-19B9-E0B5-D4F960CAB5DB6704</p> <p>http://healthtech.globalwatchonline.com/epicentric_portal/site/healthtech/menuitem.eaa27dcd4e81c3bec5cbc10673e8a0c/</p> <p>http://www.nihr.ac.uk/industry/Pages/default.aspx</p> <p>http://www.mediinkuk.com/</p> <p>http://www.innovations.nhs.uk/</p> <p>http://www.nic.nhs.uk/</p> <p>http://www.crncc.nihr.ac.uk/index.html</p> <p>http://www.nihr.ac.uk/infrastructure/Pages/default.aspx</p>
<p>Industry needs better ways to find the right people to work with</p>	<p>HealthTech & Medicines KTN Special Interest Group on Medical Device Clinical Studies</p> <p>NIHR Clinical Research Network Co-ordinating Centre</p> <p>NIHR Office for Clinical Research Infrastructure</p> <p>MediLinkUK Innovation Hubs National Innovation Centre</p> <p>NICE MTAC</p>	<p>http://healthtech.globalwatchonline.com/epicentric_portal/site/healthtech/menuitem.5617cbdaeedb6d3dc648dc10673e8a0c/</p> <p>http://www.crncc.nihr.ac.uk/index/industry.html</p> <p>http://www.nihr.ac.uk/infrastructure/Pages/default.aspx</p> <p>http://www.mediinkuk.com/</p> <p>http://www.innovations.nhs.uk/</p> <p>http://www.nic.nhs.uk/</p> <p>http://www.nice.org.uk/aboutnice/whatwedo/aboutmedicaltechnologies/medicaltechnologiesprogramme.jsp</p>
<p>Everyone needs to get better at designing</p>	<p>NICE MTAC</p>	<p>http://www.nice.org.uk/aboutnice/whatwedo/aboutmedicaltechnologies/medicaltechnologiesprogramme.jsp</p>

research projects appropriate to MedTech	NIHR Clinical Research Network Coordinating Centre HealthTech & Medicines KTN Special Interest Group on Medical Devices Clinical Studies MedilinkUK	http://www.crncc.nihr.ac.uk/index/industry.html http://healthtech.globalwatchonline.com/epicentric_portal/site/healthtech/menuitem.5617cbdaeedb6d3dc648dc10673e8a0c/ http://www.medilinkuk.com/
Maintaining/improving transparency of costs and processes	NIHR Costing Template	http://www.crncc.nihr.ac.uk/index/industry/costing.html
Need to establish a community of med tech expertise	HealthTech & Medicines KTN Special Interest Group on Medical Devices Clinical Studies NIHR CRN CC	http://healthtech.globalwatchonline.com/epicentric_portal/site/healthtech/menuitem.5617cbdaeedb6d3dc648dc10673e8a0c/ http://www.crncc.nihr.ac.uk/index/industry.html
How to do registries and other non-standard studies cost effectively?	For consideration within HealthTech & Medicines KTN Special Interest Group on Medical Devices Clinical Studies	
Need to be aware of and address global research questions	For consideration within HealthTech & Medicines KTN Special Interest Group on Medical Devices Clinical Studies	

<p>Issues relating to data protection competencies in research sites</p>	<p>To be discussed with the NIHR research support service team</p>	
<p>Getting research designed to meet user questions not sales objectives</p>	<p>HealthTech & Medicines KTN Special Interest Group on Medical Devices Clinical Studies</p>	

Appendix B

Speakers' Presentations

See separate documents

Appendix C

Break Out Discussion Groups

Character of Tables

Table	Chair	Character
Table A	Dr Clare Morgan (NIHR Clinical Research Network Co-ordinating Centre)	Large companies
Table B	Jenny Gray (NIHR Clinical Research Network Co-ordinating Centre)	Large and Medium Companies
Table C	Dr Sue Bourne (UK CRC)	Innovation Support and Woundcare
Table D	Dr Matthew Hallsworth (NIHR Clinical Research Network Co-ordinating Centre)	Diagnostics
Table E	Sue Dunkerton (HT & Medicines KTN)	Smaller companies and innovation people
Table F	Dr David Gleaves (MidTECH Innovation Hub)	Smaller companies, universities, trusts and innovation people
Table G	Dr Janette Benaddi (Medvance Ltd)	Innovation support organisations
Table H	Dr Kieron Day (St Jude)	Innovation support organisations
Table I	Adrian Warner (TrustTECH/ACTNoW)	Innovation support organisations
Table J	Jill Dhell (Dept of Health)	Mixed

Appendix D

Breakout feedback to Audience

Feedback at end of Breakout Session 1: Research Design Issues

Question 1: What are the burning issues within the clinical research environment that companies need addressed?

Group A

- Need for standardisation of R&D Depts. and where the money received goes
- IRAS – fear of ticking the wrong box
- Continual changes in the environment

Group B

- Design complexity (e.g. Standard of care) so we can plan effectively
- How to find the best sites (depends on the exact study)
- Variability in fees
- Companies see the system as fragmented
- How to do Primary Care research (this is going to be a major shift in focus for the NHS in future) – where to get good relevant health economics data etc

Group C

- Need to simplify and standardise the process, and then communicate it effectively
- Minimise costs and timeframes
- Ethics Committees: composition of committees and processes which improve understanding of the real issues

Group D

- We need a map, and then someone to hold your hand to guide you through it
- Simplify linkages to R&D Depts: especially training and education; what is involved in specialist areas (e.g. Telemedicine)
- What does 'benefit' mean?

Question 2: What do companies perceive to be the barriers to undertaking clinical research in the NHS?

Group E

- Ethics Committee: clarify what their purpose is
- Silo Budgeting issues and a better understanding of the whole patient pathway
- Motivate researchers in adoption related research

Group F

- Different Industry communities
- New companies and companies new to the healthcare market
- A wider definition of clinical studies is needed

Group G

- Building a better understanding of the MedTech industry in the user community
- Problems of getting into the correct R&D offices
- Industry understanding of the processes and organisation involved in clinical studies: one needs to understand the agenda of all the players

Question 3: How do companies currently go about designing med tech industry clinical research studies? Where can they get help?

Group H

- Large companies do it in-house as they have much experience: SMEs have much more difficulty, particular awareness and finding funding

Group I

- Small SMEs evaluating clinical need in an affordable way
- Funding
- Accessing appropriate clinicians

Group J

- Need for a comprehensive and up to date map of people/organisations which could help.
- Proactive training on ISO 14155
- Explanation of the context in which technologies will be used and evaluated

Breakout 2:

Questions:

*What are the main problems companies face in getting clinical studies done?
(NB: this should address both experienced and inexperienced companies)*

What changes would do the most to make this situation better?

Feedback at end of Breakout Session 2: Where are the gaps?

Initial comments captured:

- Problems of studies being carried out in sites which do not have company products in use | : potentially a high barrier for new entrants
- Need to consider registries and other types of study

Group A

- Studies need to be driven by global market considerations, not just UK
- Need for linkages to the research capability programme

Group B

- Need for focus on recruitment
- Links between Sales and R&D in companies can cause compromised study design
- Accumulated feasibility data
- R&D needs to be seen as a critical Trust capability
- How to support flexible infrastructure

Group C

- Focus on feasibility and recruitment in research designs
- Research team staffing and retention for duration of study
- Investigator naivety
- Excellent communications on progress and all other matters throughout study
- Need for a diverse community
- SMEs need to know how to get their studies adopted

Group D

- How to get to the starting blocks: who, when; what questions to ask?
- Better at discussing problems
- Better at marketing UK's clinical study capability
- Map of expertise to get studies of the ground (NB: different from Pharma model)
- Awareness of where to find appropriate ethical skills to undertake special technical studies

Group E

- What is the right research question?
- Priority in delivering results
- Ability to accommodate modifications to a product during a study process
- Research passports (make them work effectively)
- Access to people who can 'pilot' a study through the barriers
- Improving research design competencies
- Possibility for earlier study concept engagement with CLRNs (esp. for non-Pharma studies)
- Better education for all involved in specific issues

Group F

- Recruitment problems
- Solving high priority 'derailers'
- Better research intelligence network (e.g. EDGE)
- 'Research' label makes many studies sound too grand for simpler trusts

Group G

- Costing template – lack of knowledge of range of studies to be done – difficult to communicate realities with R& Depts.
- R&D approvals – support Trust in making positive decisions to go ahead with studies – network of knowledgeable clinical advisers
- Routing people to the right experts
- Earlier engagement to help determine what is the correct study to do

Group H

- Research design – access to a network to design the research question/hypothesis
- MHRA type work deadline
- Funding for studies
- Maintaining momentum – use of metrics on centres

Group I

- Regional works best – but it is patchy
- NHS Access – want a consistent approach – NIHR & access & adoption etc

Group J

- Need to work with departments who are not traditionally involved in Pharma studies
- Hospital Engineering Department variability of approach for non-CE marked product use
- Issues relating to secure storage for non-CE marked products
- Data protection issues – anonymisation (how to ...)
- Private healthcare provider involvement
- Post Marketing surveillance and its role in NIHR type research
- Frequent movement of staff in/out of research team

- How to share essential learning

Appendix E

Detailed Notes made on Group Report Sheets

This section aims to capture all notes made by the groups on their work sheets; unlike the feedback sessions, they are not prioritised.

Session 1: Research Design Issues

What are the burning issues within the clinical research environment that companies need addressed?

- Variability between R&D Depts. (A);
- Differences in R&D depts. time to respond cause issues (B);
- Time taken to respond (A);
- relationships for PIs with R&D Depts. (A);
- mixed understanding of mCIA (A);
- competence (A);
- need for training(A);
- **need standardisation of R&D Departments & processes (A);**
- Lack of feedback mechanism (A);
- R&D control & training -> standardisation (A);
- **R&D variability in terms of time (B);**
- **Simplify or standardise processes and communicate what's available and how to start (C);**
- **Address variability between centres including introducing stand and predictable costs and timeframes (C);**
- IRAS - Lack of feedback mechanisms (A);
- not enough training or knowledge on it (A);
- **fear of ticking wrong box and the implications for study time lines (A);**
- controlled updates - not frequently and randomly (A);
- **IRAS requirement for radiation box** - standard of Care -> ARSAC (A);
- Transfer out but lack of transparency of what's happening locally (A);
- **Lack of route for escalation of problems (A);**
- MHRA - positive (A);
- *Ethics* - Remaining issues (A);
- need for training of ethics committees (A);
- 12 too big (A);
- Ethics - negative loop if study is initially rejected (A);
- Ethics - length of application, protocol/peer review, experience of med devices, peer review, patient information sheets (C);
- inappropriate application of same rules to all devices regardless of risk; best ethics committee for med tech orthopaedics is not one of the designated ones (A);
- Circularity of process proof of concept -> ethics -> trial - How to get out of this loop? (C);
- **Ethics - composition of ethics groups, expertise of committees, need opportunity for clarification during application not just get to final decision at end, appeals process (C);**
- Standard of Care - mixed across NHS (A);
- **Cost (B);**
- Fees & variability (A);
- Fees- up-front & fixed costs but lack of recruitment (A);
- fee charged per patient + for research nurse (A);

- costs kick in from time of developing protocol (C);
- Cost - need predictability and reduced variability (C);
- Increased costs do not correlate with speed or quality (C);
- training for NHS in how costings template works (I);
- where is money going from per patient fee if research nurses not available in the system (A);
- **Transparency of costing (C);**
- **Finding appropriate sites/partners: Who to go to? Where to start? varies according to project development, company size and internal expertise (B);**
- need good relationships between company and centres; research registrars seen as valuable informed contacts (E);
- difficult to find clinicians willing to do research (E);
- structure does not encourage research, no incentives for younger clinicians to do research (E);
- interactions between universities and NHS (I);
- How do SMEs get help? Template protocol, terminology, where to start (C);
- R&D Approvals: 14d - 1yr (C);
- France & Germany don't have R&D Approvals step (C);
- need one stop and one review for R&D approval (C);
- How to get a study adopted onto the Portfolio? (G);
- Where to start, who do they talk to initially, focus on R&D (G)
- **Gateway into NHS and navigating regulatory landscape; keeping a study on track (I);**
- Timelines (J);
- Needs consistency across bodies e.g. R&D, ethics, etc (J);
- Keeping a study on track - SME resources limited (J);
- needs a clear map or processes/organisations (D);
- Device-specific network or UK speciality group (D)
- How to collect evidence for NICE? Widening of scope Clarity on what does benchmark mean (D);
- What evidence is needed? Is there a need for an RCT? Is it appropriate given the time it takes? Difficulties in doing "blind" studies in devices (I)
- Easier elsewhere (E);

What do companies perceive to be the barriers to undertaking clinical research in the UK?

- Fees: Variable NHS set-up fees (B);
- Ethics - training in devices (B);
- **Ethics committees - Similar rules applied to all device risk levels, not set up to support the innovation agenda (E)**
- Fragmented system - Requires an NHS medical device "road map" (B);
- Fragmentation - needs clear pathways (C);
- Needs person to provide a single entry point, not a process (F);
- Design - Need for signposting to research design support, access to health economics expertise needed (unlikely to be held internally) (B)
- **Cost and speed both need improving (D);**
- Cost - escalation of costs for research trials, How to define the parameters of the research study? (E);
- variability in costs across sites and justification for them (J)
- MHRA advice conflicts with R&D advice on CE marking (D);
- R&D understanding is local (D);
- R&D are risk averse (D);
- **R&D need to see the whole package (D);**
- **Education & Training - need to raise awareness of devices (D);**
- **Interpretation of risk - local vs. national (D);**
- **Silo budgeting continuing to be an issue affecting research (E);**
- Getting data for whole patient pathway, Not being captured (E);
- **Need adoption to get research encouraged in the UK, Companies need to access for global markets (E);**
- metrics to demonstrate take-up and benefit is used for PMS (E)

- **Three communities: large med tech (pharma-like), SMEs, companies diversifying into healthcare - Which community has the innovators? (F);**
- R&D Depts don't understand where industry is coming from & industry doesn't understand where R&D depts. are coming from (G);
- Industry studies are put to bottom of pile (G);
- Risk averse and confusion behind clinical areas, other depts. (G);
- Primary Care - move to Primary Care for many indications (B);
- monitoring of health economics data in Primary Care (B);
- Primary care needs to be engaged in research (G);
- **Primary Care - moving out needs attention engagement in research (G);**
- Interactions between universities and NHS (I)
- NHS priorities and procurement issues (I)
- Lack of consistency across bodies: ethics, R&D etc (J)
- Improving training needed in research governance for both NHS and industry (J);
- Lack of consistency across bodies: R&D, ethics, etc (J)
- Very few investigators feel accountable to the trust to keep a commercially-sponsored project on track. This is compounded by inexperienced CROs and absent PIs. (J)
- Use on-line reviewing to speed up process (C);
- Increased cost does not correlate to speed or quality ! (C):
- Concern that payment to patients can count as coercion (D);
- Clinical input early on in design (G);
- Costs - perception. Some R&Ds have to fund themselves. Small companies don't have resources (G);
- How R&D and ethics work, how costings work, interactions between universities and NHS (I);

How do companies currently go about designing med tech industry clinical research studies? Where can they get help?

- If don't have expertise then have to work with CRO. Impossible to work out for self (C);
- There is no specific help for diagnostics manufacturers (D);
- Mostly in-house but this is not always trusted as best design and good evidence (E);
- Research registrars are excellent resource (E)
- For trials - good Trusts, RDS (if portfolio), universities (Brunel) (F);
- **SMEs can utilise the Innovation Centres (H);**
- **Clinical evaluation - MHRA, R&D by external consultants (H);**
- **SMEs - Research Design Centres (H);**
- **large organisations tend to complete process independently (H);**
- **Start-ups refer to Innovation Hubs, KTN (H);**
- **Small companies don't know who to approach or the level of evaluation required (I);**
- Evaluating the clinical need b) setting the appropriate research question c) collecting appropriate evidence within available funding (I);
- **Need to have a clinician interested and on-board (I);**
- NHS buy-in leads to access to RDS Otherwise inaccessible to industry (I);
- Company has to pay for design advice - current investment difficulties (access to pilot level funding) (I);
- **Difficulties in doing "blind" studies in devices (I);**
- NIHR funding through NHS clinicians/academics (I);
- **Finding the right/friendly organisation/individual e.g. clinician/investigator (Due diligence required): (R&D Dept, Medilinks, KTN, Innovation Hubs) (J);**
- **look at competency by Trust (J);**
- **Research Design Services (but generally not industry-focused) (J);**
- NICE Single Evaluation Pathway, in future, will help give clarity for what evidence is required (J);
- Need to be proactive in training NHS to understand the implications for PMS in amendments to ISO 14155 (J)
- Companies don't understand the Data Protection Act and its implications for NHS investigators and may inadvertently request data collection that would not comply (J);
- Company needs advice on what business case is required for forward purposes and how this impacts the protocol questions (J)

- Need portfolio of research protocols - 2008 Guidance (E);

Other observations

- Lack of trained research co-ordinators leads to delays in submissions (A);
- Company's marketing strategy has major impact on site selected for research study (A);
- Best ethics committee for med tech orthopaedics is not one of the med tech flagged RECs (A);
- Payment for EQ50(?) registration for med tech companies i.e. long term outcome data (A);
- Focus on a few PIs to provide nurse resource to kick start new sites (A);
- MHRA won't start 90 days until payment is made (A);
- Use on-line reviewing to speed up the process (C);
- Adoption onto NIHR Portfolio difficult and takes long time. Understanding of how to access and what benefits are needs to be communicated (C);
- Little knowledge of CLRNs and what they do (C);
- Early days for Healthcare Technology Co-operatives - need more comms (C);
- Comms - internet useful but too much to wade through, use Medilinks to promulgate + ethics, have standard pack of information at centres/R&D offices (C)
- Internet useful but too much info to wade through (C);
- Pathway sometimes confusing, can be slow, lots of acronyms, implementation across Europe is very diverse (D);
- Some medical device studies are seen as "dirty research" (G);
- Lots of acronyms (D)
- More visible navigation in other countries (D);
- Companies need to Access for global markets (E)
- Not understanding how to enter process (often turned away because not in right way) (E);
- If industry pays, it is seen as having a vested interest (E);
- Many specific issues that are device-focused and related to the nature of the technology or product e.g. NHS does not recognise air quality as a measure, only contact surfaces, e.g. wound management (E);
- Need for innovation in methodology (E)
- Great potential USP (F);
- Defining what is meant by "clinical research" (F);
- More personal approach (less process) appropriate for SMEs and the established companies diversifying into healthcare - can be provided regionally (F);
- Think about sharing risks (G)
- Med tech has to update its profile (G);
- General issues with lack of awareness and funding (H)
- Company has to pay for design advice - access to pilot level funding is challenging, especially in current financial climate (I)
- NIHR funding is accessed through clinicians/academics (I);
- need to have a clinician interested and on-board (I);
- NHS buy-in enables Research Design Service support to be accessed (I);
- Companies do not always want to use mCIA unmodified for PMS because not "research" and does not go into IRAS system (J);
- NHS Trust buying devices for PMS study can raise procurement/contract issues (J);
- Orthopaedics benchmarking - resurfacing & replacement wrong (A);
- **Positive of changes happening - motivation towards same goal, positive momentum, single application, UK commitment (A);**
- Access to health economic expertise unlikely to be internal, even with companies with research design internally (A)
- What is right evidence for new NICE process? (D);
- SMEs use favourite network to get trials undertaken but will become more difficult (E);
- Metrics to demonstrate take-up and benefit -> post market surveillance, industry and clinicians available at right time (E);
- Industry trials not seen as route for NHS to make money (E);
- definition of medical device (E);
- Research registrars seen as valuable and informed contacts (E);
- Difficult to find clinicians willing to do research (E);

- Why no SMEs here? Where does innovation arise from? (F)
- Great potential for USP (F);
- Is the Single Pathway the answer? (F);
- Single entry point for SMEs (F);
- Need person not process KTN? (F);
- Clinical needs - danger that we address all as clinical trials (F);
- Difference between pharma post-trial monitoring and med tech -> large numbers (F);
- Fewer incentives (F);
- Ethics - echo presentation (F);
- Failure to understand (F);
- Not knowing (G);
- Perception is pharma. Med tech has to update its profile. Industry does not get over our threshold (G);
- need to bring in timelines for R&D (G);
- R&D teams don't have skills & leadership & is not a priority (G);
- Need to take more entrepreneurial view without endorsing. Think about sharing risks but could be issues. Disproportionate amount but could have a sliding scale (G);
- NHS are resistant to SME approach (H);
- Complexity of work (H);
- Identifying clinicians (H);
- Lack of route map (H);
- Awareness and funding (H);
- OLS fast-track for innovation, by-passing NICE? (I)
- Need to be proactive in training R&D Departs in implications of Revision to ISO 14155 for PMS (J);
- PMS - companies don't always want to use mCIA and it isn't research - scope for a revised version (J);
- Advice on what business case required for forward purposes -> how it impacts the protocol questions (J);

Breakout 2: Where are the gaps?

What are the main problems companies face in getting clinical studies done?

- Funding for smaller companies (I);
- Cost (A);
- 70% overhead on costing template (A);
- Misconception of costs of running study (particularly inexperienced companies) (C);
- ACTNoW prominent investigators and are they research active. Very valuable resource but patchy at moment (C);
- Time (A);
- Delays in study start-up (I);
- Difficulty in obtaining NIHR Adoption- perception that dependant on type of funding; and that no interest in smaller projects (I);
- Ensure R&D a key Trust strategy and CEOs understand importance of performance management (B);
- Recruiting adequate numbers in right time-frame (over-optimistic at start, patient drop-out) (C);
- Robust feasibility isn't done well (C);
- Be realistic about number of patients that can be recruited (C);
- Access to NHS - some trusts have Trial Units but still need to work with R&D, trusts have different R&D procedures and resources (I);
- **Can only go to sites using the product (A);**
- **Global standards** impacting upon UK practice (A);
- Only PIs with experience of a specific device can be used, Increased UK costs seen as inducement as sales = delivery of patients (A);
- General company resource (A);
- Study management and recruitment (I);
- Different costing model - not in SME/company thinking & not budgeted for (F);
- Costs (G);
- Designing trials: Lack of understanding and knowledge of different types of study design and that devices are modified/changed with a short product lifecycle - incremental improvements. Is it research? Diversity innovation is gradual (G);
- R&D approvals (G);
- Routing people/communicating (G);
- Earlier engagement (G);
- Protocol design (H);
- Long delays for SMEs from initial visit to starting work (6m typical) (H);
- Funding - without VC support: path is not clear (H);
- Funding - monies dedicated by NHS for research is limited (H);
- Maintaining momentum for study inclusions and FU ongoing once regulatory requirements met (H);
- Designing trial (I):
- **Where do registries and PMS fit in?** Needs to be reflective of current practice (A);
- Equipose/binding (A);
- Close links with sales depts./R&D in choice of sites, clash of strategies (B);
- Ensuring product or study design is right in first place (J);
- Staff changes and loss of experience leading to delays to study (J);
- Patient recruitment and active and engaged investigators (J);
- Realistic feasibility (B);
- Gaining research passport - variation between Trusts, varies depending on research, which affects time for studies (E);
- Obtaining the right research question, understanding competency gap to do right studies, carrying weight, data for QALY/right evidence (E);
- Will NICE/CEP Guidelines be too prescriptive? (E);

- Not enough priority given to research over and above day job, needs motivation and incentives (E);
- Change in product design during clinical trial (E);
- Ethics approval for an iterative design process - prototype validation before trials (E);
- Evaluation trials and clinical studies Centre at [named location] refusing businesses that are commercial (E);
- Leading centres can get over-researched e.g. 1 person with 2 leg ulcers in 2 different trials (E);
- Routing people to the right experts - people are lost in the system and get misdirected; lots of information and different groups. Requires clarity - Too much information (G);
- Earlier engagement at earlier stages to guide companies - It's not "just research" (G)
- Lack of research nurse/staff infrastructure (B);
- supporting staff - availability, expertise, retaining staff in uncertain times e.g. funding for posts often not long term (C);
- Research nurses retaining them is an issue (C);
- Disconnect between Trust wanting money and delivery loop (B);
- Dialogue with ethics (B);
- Expertise/education of investigators (C);
- Investigators can be quite naïve about what is involved in running a study.(C);
- Identifying the clinical champion (I);
- PIs not understanding the research process (J);
- Not joined up (D);
- very different to pharma (D);
- Need engineers, physiotherapists etc, who are in short supply (D);
- How do we communicate these innovations to audience - marketing - a package (D);
- Variation in risk averseness of Trust Medical Physics Depts to granting permission for use of non-CE marked active medical device under trial (J);
- Staff changes/loss of experienced staff member who had the competence to conduct the planned commercial study (J);
- No central repository for non CE-marked medical devices under study (as most not relevant to pharmacy dept) can lead to non-standardised approaches to preventing inadvertent use that may adversely impact on trial set-up(J);
- Many med tech studies need to take place in Primary Care and the Community (J);
- Physio studies are PCT or Community studies (J);
- Early on need to know who to talk to, when and what to ask (D);
- NICE announcements can make a study unnecessary (J);
- Disconnect between the trust wanting money and the conduct of the study (B);
- Dialogue with ethics (B)
- All the new initiatives and infrastructure is great but companies need their idea/product/protocol at a certain stage to interact with these organisations. For companies that are not yet at this stage they need to know who to talk to, when to talk to them and what to ask so that they can be understood and heard.(D);
- Better communication needed - It has been too passive. Need more marketing approach to get the message about what has changed and the opportunities need a more active marketing approach (D);
- The pharma model often does not fit for medical device research. Two e.g.s: i) Core infrastructure teams/expertise - "Clinical" is usually understood to mean "medical". For devices sector core expertise includes engineering, software design, physics, etc. Finding, funding and retaining this expertise is a challenge. A map of where this experience currently is would be a good start.(D); ii) Research nurses in the Networks are designed to have generic skills. This works well for pharma studies. However, for device studies the research nurse may need detailed technical knowledge to work with the device with patients)(e.g. quite technical skill needed to use an insulin pump) (D);
- Lack of recognition within Trusts that a planned change in the way of operating a routine service could kill an agreed commercial research study (e.g. the national move to centralised sterile service departments made a study involving a specific tray layout involving novel sterile surgical instruments so difficult to carry out from the contractual perspective that the UK was abandoned). Small studies may be the most vulnerable (J);

- Issues with the Data Protection Act (e.g. Trust invoicing requirements to the company breaching the Act (J); site not anonymising images; radiobiology/histology reports including DPA non-compliant information in reports submitted to the company) (J);
- NHS use of private hospitals to reduce waiting lists - patient being recruited to trial in NHS but seen by PI in private hospital where trial technology was located (J);
- Amendments to ISO 14155 will raise the requirement for PMS, consent is needed for data transfer in PMS but the study itself does not ethics or R&D approval - still needs a contract, Indemnity in PMS - not everything in the mCIA is relevant (J);
- Promised - unrealistic delivery or feasibility (F);
- Recruitment (F);
- Commitment or priority e.g. swine flu (F);
- Resource issue (F);
- Inappropriate - poorly informed - early engagement (F);
- Different costing model not in SME or company thinking but having implications for budget, naivety (F);
- Maintaining momentum for study once regulatory requirements met (H);
- **Other comment:** Commitment/priority e.g. swine 'flu' (F)

What changes would do most to make this situation better?

- SHAs' regional innovation Fund (I);
- working at regional level works best (more and better relationships) (knowing who is on your patch) (I);
- Cost effectiveness focus, payment on delivery, other agreement i.e. confidentiality agreements, justification of use of specific PIs (inducement) company issue (A);;
- terminology & explanation sheets (A);
- SMEs need to get studies adopted as they need NIHR support that's available and thereby to be helped through the system (C);
- ACTNoW needs expanding. It's a valuable resource (C);
- **Consistency** within CLRNs - some have central structure; some devolved structure (I);
- specifically CSP issues and differences in adopted & non-adopted studies + problem with amendments in CSP (I);
- Dependent on type of funding - smaller projects no interest (I);
- Communication - general knowledge of what's going on and what's available isn't well-known. Today's audience is really good mix. Can they be brought together again or more frequently. KTNs could be a route. Need to ensure broad audience (C);
- Consistency of approach (I);
- Themes for improvement are regional working and consistency (I);
- ISO requirement - needs to sign the protocol or contract, map tender 1 or 3 yr but confidential; UK adoption of device (A);
- linking with UK (A);
- Map tender (A);
- Costing - needs to have more realism, relate to ability to pay the value of the innovation (G);
- Needs training, awareness and understanding of the device industry (G);
- Make the trust comfortable with reviewing med dev studies. They fear to make decisions. Give them support. HTCs were set up to do this. (G);
- Network of clinical advisors that can be consulted (without putting in an extra layer) (G);
- Concept of Research Design Service (mini) for medical devices (G);
- Network interaction to help develop it (H);
- MHRA utilises 60 day "clock". Why can't Trusts? (H);
- Clarity of funding routes & awareness of potential resources e.g. SBRI (H);
- Provide more moneys, develop business model and reclaim costs through IP (H);
- Better contractual arrangements publication of metrics (final and interim, league tables) research review of clinical activities (H);
- Absolute need for a map for all - large, SME, start-up and innovators (H);
- Linking with Research Capability Programme (A);

- Link with Networks to help identify research-orientated sites, particularly for registry studies (B);
- Robust feasibility and early design discussions (J);
- More use of CLRNs and database (J);
- use of CLRNs (J);
- NIHR Networks can provide info on competing studies (commercial/non-commercial study) & metrics on site delivery, provision of "real" feasibility data (B);
- Personal gateway - someone who understands to guide through the process - road map in background (E);
- Common sense re passport (national initiative interpreted differently - Monitor how it is used) (E);
- Incentivising research & co-ordinating functions beyond PI - ability to handover/changes in personnel (E);
- Better education of all doing evaluation/approvals; Systems to suit med tech (changes in product design) (E);
- Better education of all doing evaluation/approvals (E);
- Bona fide methodological (research design) processes to cover range of med devs to support study design (E);
- CRN Can there be an earlier informal [process to reinforce difference between pharma and MedTech (E);
- Need a clear pathway; engagement with the right people (G);
- Set up research facilitators linked with proposed mini RDS (G);
- Innovation Hub - pass it on to RDS (G)
- Performance management is key. Needs to be an active process to ensure delivery. Requirement throughout study cycle although at recruitment stage very important (C);
- performance management of delivery post approval and contingency planning (B);
- RDS really supporting commercial or SMEs? Perception is that they are non-commercial focus (C);
- Investigator should have training/accreditation that shows they understand need/requirements (C);
- ACTNoW- prominent investigators who are research-active - very valuable resource but patchy at the moment - ACTNoW needs to be expanded. It is a valuable resource (C);
- Different or lack of support in some regions (e.g. no Medilink in London) (I);
- Would like 'seamless' (D);
- Needs training and education + capturing the audience (D);
- needs more cross-disciplinary working (D);
- map of technical expertise (D);
- need more specialist staff (D);
- Co-ordinated information package (D);
- Need more cross-disciplinary working (D);
- Map of technical expertise (D);
- Map of technical expertise; need more specialist staff; needs more cross-disciplinary working (D);
- Network of clinical advisors that can be consulted (without putting in an extra layer) (D);
- Better contractual arrangements, publication of metrics (final and interim; league tables) research review of clinical activities (H)
- For CRN, Can there be an earlier informal process to reinforce the difference between pharma and med tech? (E);
- Performance management of delivery post study approval is key (B); (C);
- Performance management needs to be an active process to ensure delivery, Requirement throughout the study cycle although at recruitment stage it is very important (C);
- Contingency planning (B);
- Ensure R&D is a key trust strategy & CEOs recognise the importance of performance management (B)
- Improved dialogue and awareness of the R&D Portfolio by the Trusts' administrative function - and vice versa (J);
- Industry liaison Med Tech - mentoring at regional level (F);
- Confidentiality (F);
- "Scout" scheme (F);
- Good information systems - patient availability (F);
- research intelligence (R&D Office) - improved shared knowledge (F);

- penalties for non-recruitment (F);
- incentives for recruitment and delivery (F);
- Costing - more realism (F);
- pre-trial dialogue engagement (F);
- Non-academic trusts - opportunity to get involved, innovation label, new "buzzword" (F)
- Standard contract mCIA a huge benefit (A);
- Produce a modified mCIA specifically for PMS (J);
- Standard contract mCIA seen as huge benefit (A);
- Are the RDS supporting commercial/SMEs as the perception is that they are non-commercial focus? Concept of a (mini) RDS for medical devices (G)
- Absolute need for a map for all: large, SME, start-up and innovators (H)
- Raise awareness of the need to consult R&D in the clinical/service change decision-making process within Trusts (J);
- Share learning from individual bad experiences to prevent unnecessary repetition at other sites (J);