University of Birmingham Business Club
Breakfast Briefing

Innovation in Medical Devices

14 May 2019
Collaboration with UoB to Develop Medical Devices

Dr Naomi Green, University of Birmingham
Adam Sheward, Kimal Plc
Biomedical Engineering Research Group

- Design
- Biomaterials
- Medical Devices
- Mechanical Testing
- Additive Manufacture
- Medical School/NHS
- Computational Modelling
- Industrial Collaboration

University of Birmingham
College of Engineering and Physical Sciences
VASCULAR ACCESS

PROCEDURAL SOLUTIONS

BRITISH OWNED

INTERNATIONALLY KNOWN

KIMAL

OUR STRATEGY

50 YEARS OF HISTORY

BUILT ON RESPECT

DELIVERING HEALTHCARE INNOVATION
At the heart of Kimal is our passion for delivering innovative solutions & exceeding our customers’ expectations

**PROCEDURAL SOLUTIONS**
- Increase International C.R.P business by 300,000 units
- Maintain market share and increase profitability of domestic C.R.P business
- Increase European market access and market share
- Double the volume in key Surgical Specialities, with 200,000 additional units

**VASCULAR ACCESS**
- Become a top 3 CVC player with 10% market in selective markets
- Market leader in delivering smart catheter technology with a commercial product available in 3 years
Vascular Access

To improve patient safety through innovative vascular access products.
Acute haemodialysis catheters that give you peace of mind from catheter-related risks.

Maximise your options whilst minimising the risks to your patients with all the unique features of Altius® family of catheters.

Combine Kimal's innovative catheters with our range of comprehensive procedure packs for maximum patient safety.

Peripheral inserted central catheters may be used to administer fluids, antibiotics, chemotherapy, parenteral nutrition, pain management drugs, and for blood sampling.

Midline catheters reduce the number of repeated cannulations which reduces patient discomfort, increases patient satisfaction and also contributes to organisational efficiency.

The complete range of chronic and acute haemodialysis catheters.
KIMAL COLLABORATIONS

Kimal are working with a number of respected individuals and establishments in order to further their development programmes some of those are:

- Longterm Material additive programmes with Ulster University
- Understanding Biofilm in catheter design - Edinburgh University

Dr. Amato De Monte
Azienda Ospedaliero-Universitaria
Santa Maria della Misericordia

Dr. Ron Daniels
Good Hope Hospital and UK Sepsis Trust

University of Birmingham

University Hospitals of Leicester
Leicester General Hospital
Main Entrance & All Wards
Restaurant
Disability Services Centre

Queen Elizabeth Hospital
NHS Trust

Great Ormond Street
Hospital for Children
NHS Trust
Context

- Looking to rationalize range of Central Venous Catheters and develop new products
Context

- Computational Fluid Dynamics not widely used in the industry to understand catheter tip design and performance but has significant potential
- Currently no capability in house to do CFD
- Only a few people in the business recognise the potential value of CFD
- Reluctant to invest in software and trained staff
Kimal/UoB Collaboration

- Knowledge Transfer Secondment from EPSRC Impact Acceleration Account
- 50% match funded by Kimal
- 6 month secondment for a post doctoral researcher
Project Aims

- Analyse performance of Kimal’s Central Venous Catheters and their competitors using CFD
- Evaluate flow rates/patterns and assess recirculation
- Identify any issues with existing products
- Use results and CFD to design an improved catheter
Two Stage Modelling Approach

Phase 1

- Simple model to quickly evaluate flow in/out of tip and side holes
- Can simulate recirculation when catheter operates in reverse mode

Phase 2

- Geometrically accurate right atrium model
- Varying physiological boundary conditions
- Can determine flow patterns across entire cardiac cycle
- Determine optimal designs and suggest potential improvements based on CFD analysis
Phase 1 Model

- Catheter immersed in blood with diameter of Superior Vena Cava
- 400 ml/min flow in to catheter

Total inflow = -347 ml/min

16.2% outflow from Side-holes

Outflow 2%

Total outflow = +353 ml/min
Recirculation

- Filtered blood is sucked back through the outflow lumen, reducing the efficiency of the dialysis
- Often worse when catheter is used in reverse
Phase 2 Model
Future Work

- Evaluate key catheters in phase 2 model
- Develop an improved catheter tip design for Kimal to add to range
- Publish work in journal paper
Benefits to Kimal

- Part funded project reduces risk to try something new
- Transfer of UoB knowledge into business
- Access to software
- Product development based on cutting edge technology
- Competitive advantage
ADVANCED MANUFACTURING TECHNOLOGIES
FOR SMARTER FACTORIES

- £7m programme funded by ERDF and the University of Birmingham
- Designed to support regional manufacturing SMEs to make their factories and products smarter using advanced manufacturing technologies
- Specific focus on the design and manufacture of medical devices and healthcare technologies
- Varying levels of support available from workshops and advice to short bespoke collaborative projects
What technologies are covered?

- Metal Additive Manufacturing
- Subtractive Manufacturing
- Hybrid Manufacturing
- Robotics & Automation
- Laser Processing
- Plasma Processing

Funded under Smart Factory Hub
Dr Azad Hussain
Medical Devices Testing and Evaluation Centre (MD-TEC)

Drew Currie
Vitabonna Development Ltd.
Medical Device – Testing & Evaluation Centre

Business Club Breakfast 14th of May 2019

Dr. Azad Hussain

Research Fellows, Medical Devices - Testing & Evaluation Centre,
University of Birmingham
Healthcare & Lifesciences Landscape

MAP KEY
1. Advanced Therapies Facility and Human Biomaterials Resource Centre
2. BioMed Birmingham (Research Park)
3. Birmingham Dental Hospital and School of Dentistry
4. Birmingham Clinical Trials Unit
5. Birmingham Life Sciences Park
6. Birmingham University Imaging Centre (BUIC)
7. Centre for Clinical Pharmacology
8. Centre for Clinical Pharmacology and Toxicology
9. Centre for Computational Biology
10. Centre for Human Brain Health (under construction)
11. Centre for Rare Diseases
12. Centre for Translational Inflammation Research (including MRC/Arthritis Research UK Centre for Musculoskeletal Agency Research)
13. Clinical Immunology Service
14. CRUK Clinical Trials Unit
15. Health Services Management Centre
16. Henry Wellcome Nuclear Magnetic Resonance Facility
17. Institute of Translational Medicine (ITM)
18. NHS Blood and Transplant Service
19. NIHR Biomedical Research Centre in Inflammatory Diseases
20. NIHR Experimental Cancer Medicine Centre
21. NIHR Liver Biomedical Research Unit
22. NIHR Surgical Reconstruction and Microbiology Research Centre
23. NIHR Trauma Management Healthcare Technology Cooperative
24. NIHR/Wellcome Trust Birmingham Clinical Research Facility
25. Phenome Centre Birmingham
26. Tommy’s National Centre for Miscarriage Research
27. University of Birmingham Medical School
28. West Midlands Regional Genetics Laboratory

MD-TEC
Medical Device Testing and Evaluation Centre

European Union
European Regional Development Fund
Medical devices in the EU in figures

- there are over 500,000 medical and in vitro diagnostic devices on the market
- the sector employs over 675,000 people in about 27,000 companies, most of which are micro, small and medium sized enterprises
- they generate nearly €110 billion in annual sales in the European market
- about 6-8% of medical devices annual sales and 10% of in vitro devices annual sales are re-invested in research every year

Regulations! Complicated, boring regulations!
We can’t go over them
We can’t go under them
We can’t go around them
We’ve got to go through them!
2017 - 2025

**2017**
- **26 May 2017**
  - Regulations enter into force

**2018**
- **26 May 2020**
  - MDR fully applies

**2019**
- **25 May 2020**
  - Certificates issued under the MDD before the MDR fully applies will be valid for up to 4 years

**2020**
- **25 May 2020 - 25 May 2024**
  - Devices in conformity with the Medical Device Regulation (MDR) can be certified under the MDR and placed on the market

**2021**
- **26 May 2022**
  - IVDR fully applies

**2022**
- **25 May 2022 - 25 May 2024**
  - Certificates issued under the IVDD before the IVDR fully applies will be valid for up to 2 years

**2023**
- **25 May 2024**
  - Devices placed on the market must be certified under the MDR

**2024**
- **25 May 2024**
  - IVDR devices on market can continue to be made available

**2025**
- **26 May 2024**
  - Devices placed on the market must be certified under the IVDR

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**MD-TEC**
Medical Device Testing and Evaluation Centre

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[European Union]
European Regional Development Fund
Classification categories MDR & IVDR

MHRA: gov.uk
Question I would have about the MDR

- Where is the information on classification?
- Where is the information on Technical Documentation?
- Where is the information on clinical data requirements?
- Where is the information on CE conformity routes?
- Where is the information on PMS?
- Where is the information on Economics operators?
- Where is the information on devices with no medical purpose?
- For self-certification, who, where and how do I register it?

  - …HAVE ADOPTED THIS REGULATION:”

- What – Articles

- How & When - Annexes
MD-TEC Support
How can we assist you?

Accelerate the translation of Research & Development:
- through ISO-accredited characterisation of devices from testing, design and manufacturing processes
- through to the testing and use of devices in terms of safety and usability in simulated clinical environments.
- provide guidance on medical device classification
- provide guidance on CE conformity assessment routes
- ensuring that you can meet the requirements of the MDR/IVDR for technical documentation.
Wider support

Additive manufacturing

UNIVERSITY OF BIRMINGHAM

HEALTHCARE TECHNOLOGIES INSTITUTE

CMD
Centre for Custom Medical Devices

RENNISHAW RenAM 500M

Medical Devices Testing and Evaluation Centre

European Union
European Regional Development Fund
Accelerating translational R&D
Enabling life science SMEs to bring products to market quickly, at less cost and with reduced risk

Looking to break through the medical technology market barriers? MD-TEC can offer a wide range of support to Life Sciences companies.

Access to a growing research pipeline around the development of healthcare technologies ranging from dressings and cell therapies through to novel diagnostic devices.

Human factors & usability testing, simulation & evaluation.

- State of the art laboratory facilities for the characterization of materials and devices manufacturing and regulation
- Trial design/IMPD preparation
- Medical device development and regulations
The Preachings On

University Hospital Birmingham

By

Drew Currie
Entrepreneur
&

NatWest Accelerator Peer Mentor
Saving Your Feet with a Revolutionary Disruptive Foot Spray

An Innovative topical foot pain-relief spray borne to be the Saviour of painful feet for everyone all over the world.

- Improve working conditions; hospital staff, retail, emergency services, armed forces,
- Promote exercise, health & wellbeing without distractive foot pain,
- Reduce Incapacity Benefit Claims & Employee Sick Days,
- Reduce pain suffered by high-heel wearing women.

But how can I save anyone when I needed saving myself!
The Salvation for Startups, SME’s, Entrepreneurs
Psalms 151: Emotional Support

- Life as an entrepreneur is always a challenge.
- Great relationships are all about great people.
- Sometimes we need someone to tell us it's ok & help share the load.
- We all need a Sister Gillian (Dr Gillian McNab), or a Sister Sinziana (Dr Sinziana Popescu).
Psalms 152: World Leading Boffins & Boffins of the Future

- Boffins like Prof Liam Grover, Dr Richard Williams & Dr Hannah Batchelor
- Expert years of academia, years of working with industry, their boffin brains bringing new angles
- Access to all lecturers, all courses, the best students; including the Boffins of the future
- MD-TEC connected me to experts directly related to my market, the technology & the ingredients
Psalms 153: Grant Support

- MD-TEC can help you write the grant & find grants you didn't even know were available
- Collaborative grants with MD-TEC have a higher success rate than sole SME applications
- Funders & Investors when they see MD-TEC & University Hospital Birmingham your viewed more favourably
- Grants allow you to create a low-risk/low-cost, credible Minimum Viable Product

*Grants are FREE MONEY! Can I get an Amen to Free Money!*
Psalms 154: MD-TEC Support vs Industry Support

- MD-TEC faster product development with compliance, clinical evaluation & regulatory guidance
- Start-up, Entrepreneur & SME’s are easy targets for industry to exploit, trust is key
- Reduce development risk to all stakeholders & getting your product to market quicker & cheaper,
- Support all under one roof; intellectual property, patent:
  - Not just medicines or medical devices, clinical studies, research, analysts,
  - Access to all the other stuff an SME needs within UoB; social media, marketing, graphic design
Psalms 155: Impressive Support
Links

......& more!
Summary Of Salvation

✓ Emotional Support

✓ Grant Advice & Support

✓ Impressive Support Links

✓ World Leading Boffins & Boffins of the Future

✓ MD-TEC Over Industry Support

Drew Currie
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Innovation in Medical Devices

Blending the Best of the Real with the Best of the Virtual – Mixed Reality for Applications in Healthcare

Prof. Bob Stone
Director, Human Interface Technologies Team
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Who Are We?

• “Established” in 2003
• Academic Personnel with 40+ Years Experience in Human Factors, Simulation (VR, AR, MR) & Telerobotics/Telepresence
• Small, Multidisciplinary Team
• Focus on Human Factors

• No Centre, No Institute, No Hub, No Expensive Lab ... Just Working with Real People, Doing Real Jobs in the Real World!
What Do We Do?
“Humans First ... Technology Second”
What Do We Do?
VR, AR and MR for Defence
What Do We Do?
Virtual Heritage
What Do We Do?
VR for Healthcare
What Do We Do?
VR for Healthcare
What Do We Do?
VR for Healthcare
Virtual environments for children with chronic pain and for distraction
What Do We Do?
VR for Healthcare
Virtual environments for palliative and end-of-life care
What Do We Do?

Bringing Defence & Healthcare Together

Serious Games and VR for Surgical Training, PTSD and “Preparing for Prostheses”
The Medical Emergency Response Team (MERT) Trainer Project

“Casualties of The Nameless”; Marco Di Lauro
MERT Training: The Challenge
(DMS / RCDM)

Can VR (and/or associated interactive technologies) deliver:

A cheaper, more transportable option?

An option with overall superior training fidelity?

Note that this challenge did not encompass the training of basic/advanced clinical skills.

Small pre-deployment team interaction training whilst working under challenging simulated contexts?

A reconfigurable quality to enable the trainer to be representative of other MERT platforms?
MERT MR Simulator Physical Body
(TraumaFX SIMBODIE)
Early Conclusion ... Interaction Assessments Were Less Than Satisfactory
New Enclosure Delivery
(June 2018)
Mixed Reality:
Augmentation of the Virtual with the Real
RAF TMW Evaluation (May 2018; Full Enclosure Blue Screen)
Different MERT Platforms “At a Click”
What’s Next?

- Medical, Force Protection and other Crew Avatar animation development and MOCAP trials
- Vibration effects
- Actual Chinook side, ramp and cockpit audio-video recordings
- New LCAC A/V recordings (littoral)
- Finalisation of new platforms and scenarios
- Future “Platforms of Opportunity”? 
What’s Next?

• Development of specific interventions, incidents and appropriate metrics
• Development of Instructor’s console and AAR process (inc. eye tracking “heat maps”)
• Integration of additional HMDs for multi-person training
• Development of environmental and “stressor” / “distractor” effects
• Smell
Thank You!

profbobstone@gmail.com
www.birmingham.ac.uk/hit-team

“Casualties of The Nameless”; Marco Di Lauro
April Cheung
Careers Network
University of Birmingham
TAPPING INTO

Tuesday 4 June 2019
Discover how our students and graduates can move your business forward.

www.birmingham.ac.uk/TappingIntoTalent
Thank you