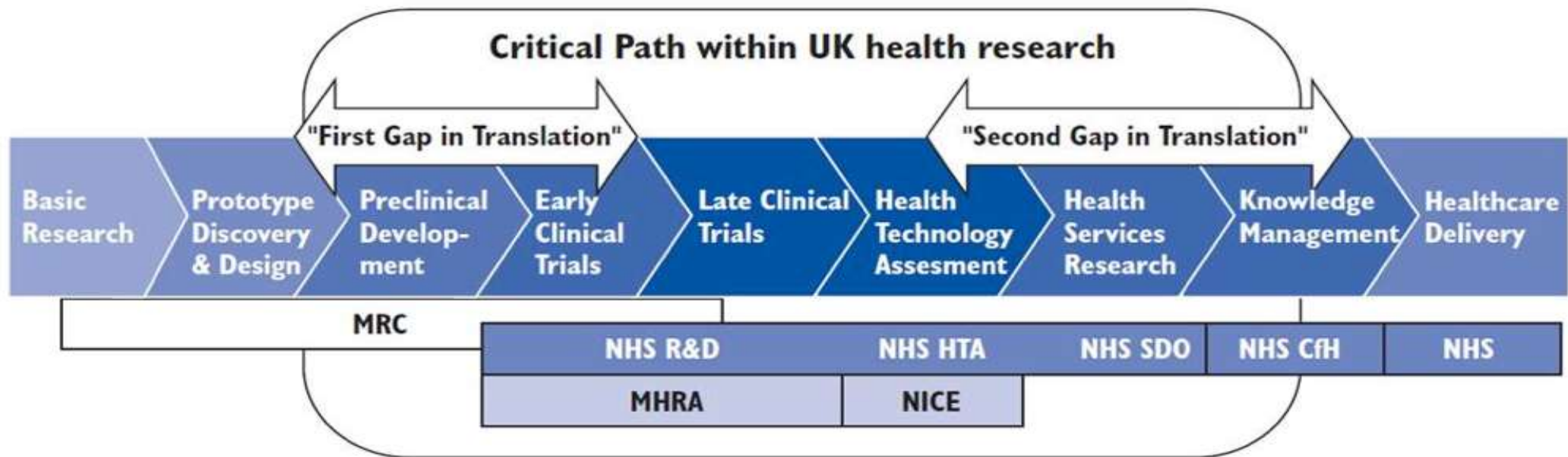


Industry, Academia & the NHS: essentials for a successful collaboration

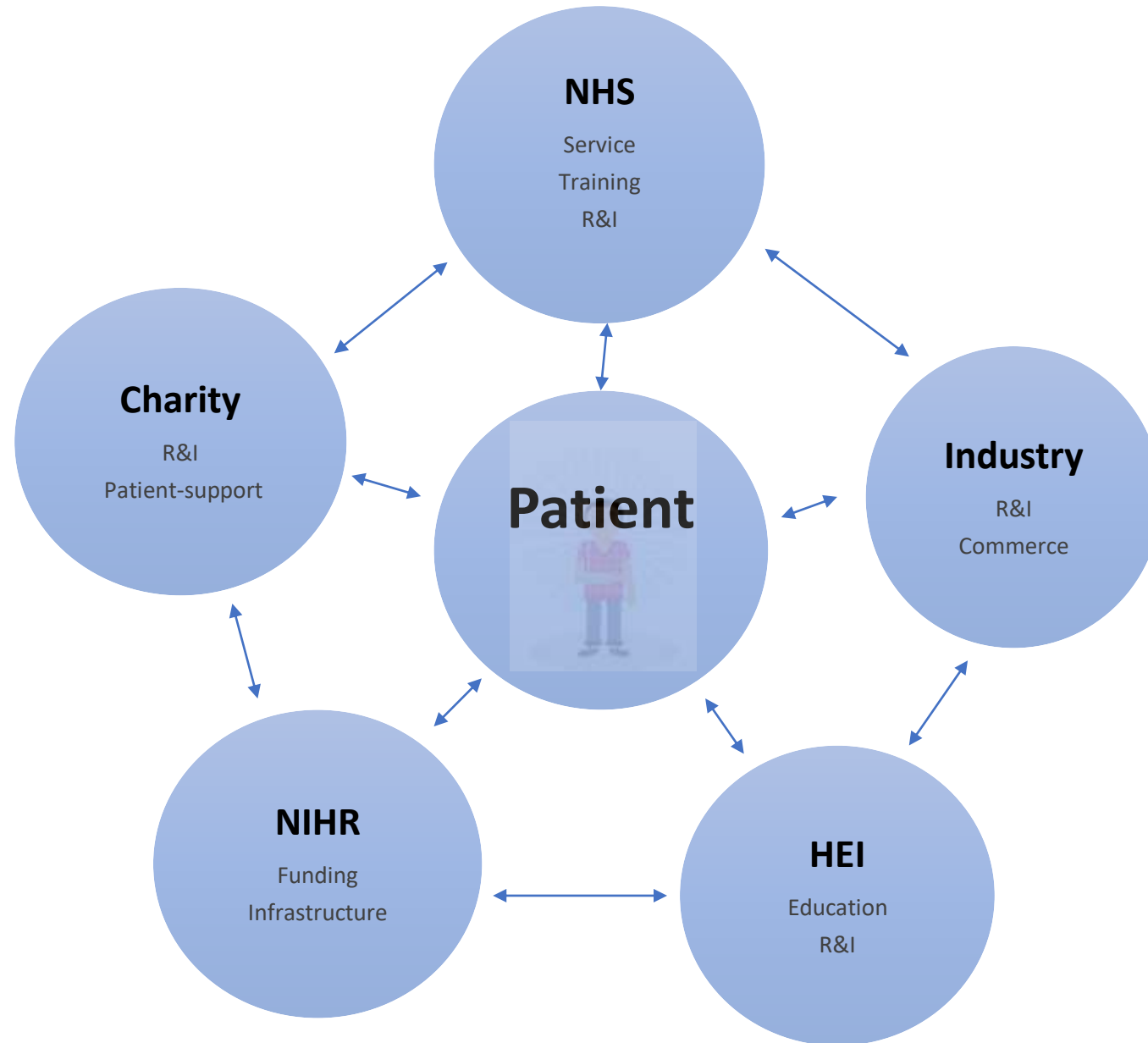
Amar Rangan

Professor of Orthopaedic Surgery



Creation of NIHR

NHS as partner rather than receptacle of research



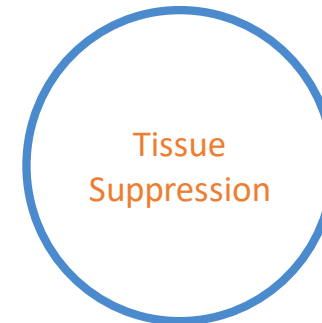
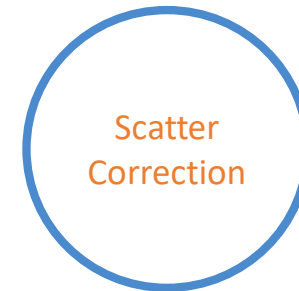
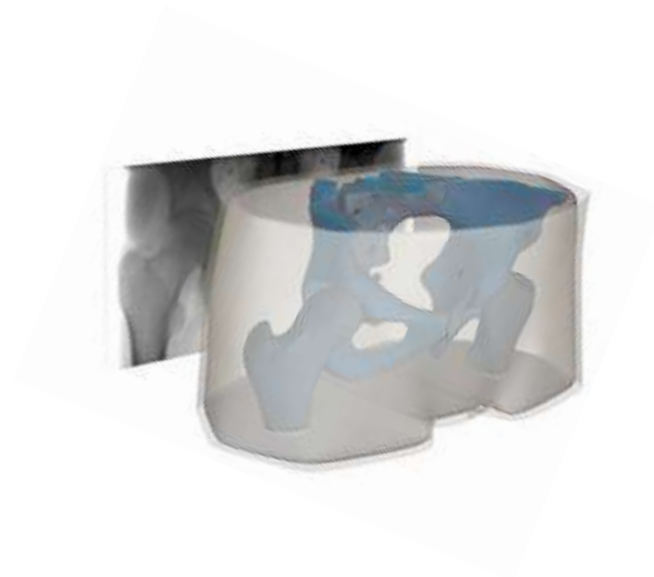
Clinical evaluation pathway – key steps

- Innovation: diagnostic, therapeutic or process
- Establish: proof of concept
- **Early engagement:** clinicians, academics & patients
 - Diagnostics North East, MIC
 - MedConnectNorth
- Define: evaluation plan & protocol
- Funding: sponsored, supported or external?
- Conduct: CTU or CRO?



- Local SME – Sedgefield tech park
- Novel imaging technology
- Image manipulation
- Reduction in radiation dose

IBEX Trueview
physics simulation
creates 3D model
of materials
ground truth



Gridless Scatter Correction



Uncorrected (no grid)



Trueview scatter correction

Tissue Suppression



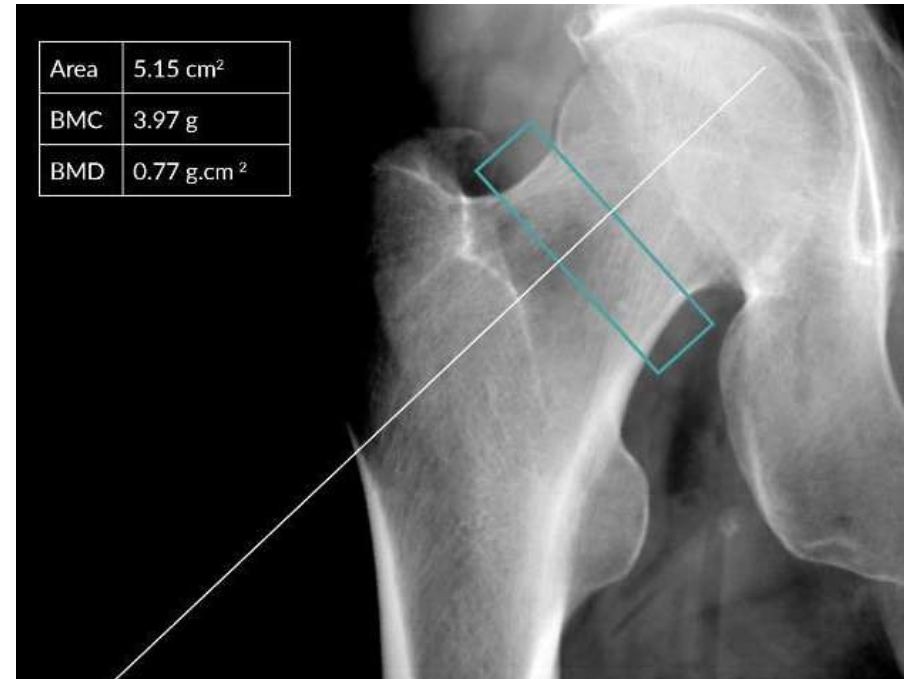
Trueview scatter correction



Trueview tissue suppression

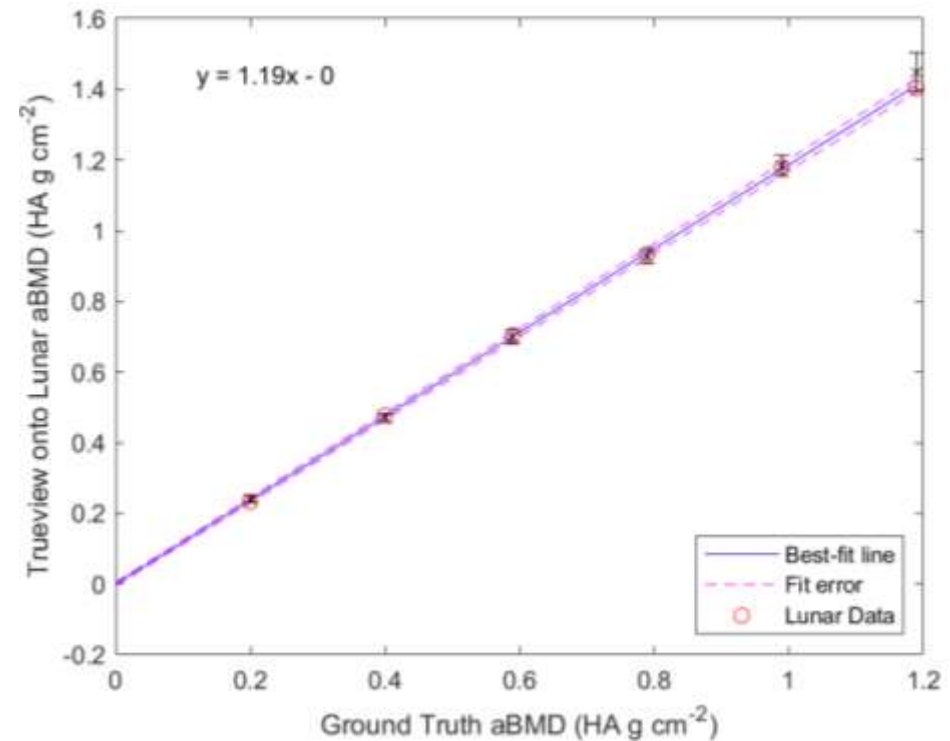
Bone Mineral Density Measurement

- BMD measurement is provided alongside standard diagnostic image
- Allows for opportunistic screening of patients using standard digital radiography
- No need for additional DEXA scan



Bone Mineral Density Measurement

- Trueview responds linearly to changing BMD
- Equivalence to DEXA outputs shown in simple phantoms





Protocol title: IBEX Trueview[®] Study

External research grant €1.6m

Funding Organisation: European Union (Horizon 2020 SME Instrument)

Clinical evaluation to include:

- Demonstration of safety and non-inferiority compared to conventional radiology
- Efficacy in detecting BMD: non-inferiority to DEXA

Linking industry with clinicians and academic infrastructure



geko™

firstkind
living science



Study Title: geko™ neuromuscular electrostimulation (NMES) device - measuring time to surgery for people with ankle fractures

- Firstkind Ltd funded and sponsored the study.
- Won both the **BIONOW** and **MEDILINK** awards for the collaboration between the healthcare sector and industry.

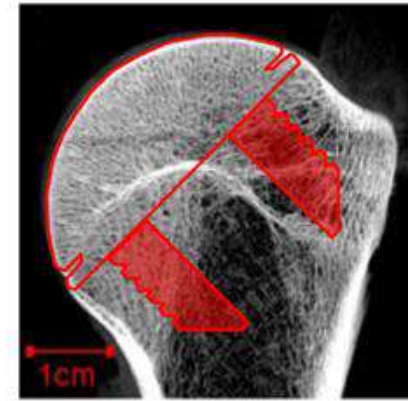


Orthopaedic surgeon Paul Baker (left) and Matthew Womack, Head of Clinical Affairs for Firstkind Ltd, a Sky Medical Technology company, with the award

<https://www.southtees.nhs.uk/news/services/trauma-patients-reap-rewards-game-changing-device/>

<https://www.gekodevices.com/geko-videos/paul-baker-james-cook-university-hospital/>

This study also achieved Successful Recruitment to Time and Target



**IRAS 219886. Full Study Title: CT 1401:
GLOBAL ICON Stemless Shoulder System Post
Market Clinical Follow Up Study**

- NIHR Portfolio adopted study
- REC approval
- Patient involvement – patient information for fully informed consent
- Completed recruitment ahead of target





Study Title: Evaluation of the SEM Scanner 200 for the Early Detection of Pressure Ulcers, a Multi-Site Longitudinal Study.

Protocol Number: SEM200-008

Study Investigator: Mr Will Eardley (UK CI)

Sponsor Bruin Biometrics, LLC

Multi-site, longitudinal study to evaluate the safety and effectiveness of the SEM (Sub Epidermal Moisture) Scanner device in detecting pressure ulcers (aka 'bed sores') in patients earlier than these would be identified in routine care.

<http://bruinbiometrics.com/en/sem>





Summary

- UK Clinical Research Infrastructure
- Early engagement with clinicians & academics:
Diagnostics North East, MedConnectNorth
- Define evaluation pathway & protocol
- Confirm source of funding
- Engage CTU, CRO as required for study conduct

“In God we trust; all others must bring data”

- *W Edwards Deming*

