Life as a University Senior Lecturer/ challenges of running clinical trials

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Dept. Oncology, The University of Cambridge
Objectives:

• Overview of Academic medicine

• (Personal) career overview

• Life as a “clinical trialist”
Academic Medicine

“Branch of medicine pursued by doctors who engage in a variety of scholarly activities”

Includes:
• Clinical work
• Research
• Teaching
• Management/ representative

Every academic has a different job description
Career Pathway History

• Lack clear entry route
• Lack transparent career structure
• Lack flexibility in balance clinical and academic training and in geographical mobility
• Shortage structured and supported posts on completion of training
• Senior academics carved their own routes (high risk)
• Lack job security
• Concern over pay parity

2004 UK Clinical Research Collaboration (gov) recommended a new pathway:
Walport, Tooke and beyond 2005

- Academic career subcommittee of MMC
- FY2 4 month to explore interest
- ACF ST1-3 generally, (25% time research) – generate results to support PhD
- PhD/ MD after ST3
- Return ST4 as academic clinical lecturer/ post doctoral researcher 50% academic
- Work towards senior academic post – clinician scientist

Flexible; NTN(A) and can drop (A) at any stage
Create new CL posts over 5 years
Will it work?

• How flexible?
• Disadvantage clinicians at later stage in career?
• Binary divide academic and non research clinicians
<table>
<thead>
<tr>
<th>Best</th>
<th>Worst</th>
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<tbody>
<tr>
<td>• Achievement</td>
<td>• 2 jobs: Academia/ NHS</td>
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<tr>
<td>• Recognition for hard work</td>
<td>• Feel behind other colleagues if “OOPE”</td>
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<tr>
<td>• Freedom</td>
<td>• Research = marathon with hard slog,</td>
</tr>
<tr>
<td>• Ask q about medical science and</td>
<td>deadlines looming</td>
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<tr>
<td>solve them</td>
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More information:

NIHR website
Academy of Medical Sciences
Deanery
BMA academic sub committee

Funders:
MRC: Wellcome Trust; Cancer Research UK
Clinical Training

Goals/ 5-year focus:

- Clinical & translational research
- Unmet needs eg prostate/ lung
- Develop Environment
- Staff (recruit, train & retain)

Career Summary (2002-2011)

RMH/ The ICR DDU
- Clinical fellow

CR-UK PhD student
- Molecular Pharmacology

St Bartholomew's
- Clinical training
- Education
- Management/ leadership
- Phase I design
Personal 5-yr aims – interview slide

Short term (0-18 months)
- “Lag” phase used for planning
- Create initial trial portfolio
  - Collaborate on research strength and priorities
  - Work with team to grow “early trials unit”

Medium term (18-48 months)
- “Pump prime” agents to tumour site teams
- Grant funding and publications
- Critical mass to unit
- Education and training

Longer term (>4 years)
- Ensure post funded and tenured
- Establish links with others eg clinical oncologists, surgical teams & palliative care (supportive therapy)
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- **5 - 9 September 2011**
- **Location**: Cambridge, GBR
- **Weather**:
  - Today: 48°F/33°F
  - Tomorrow: 48°F/37°F
  - Wednesday: 54°F/32°F
- **Events**:
  - **Monday, 5 September, 6:00 AM**:
    - Radiology Meeting, level 5
  - **Wednesday, 7 September, 8:00 AM**:
    - Early Phase Clinic
Challenges of running clinical trials – Deliverables?
Challenges of running clinical trials?

- NHS & GMC
- Clinical Trials
- Patients
- Grant/Publications
Challenges of running clinical trials:

- NHS & GMC
- Clinical Trials
- Patients
- Grant/Publications
Challenges of running clinical trials:

- NHS & GMC
- Clinical Trials
- Patients
- Grant/Publications

- Idea
- Funding
- Drug(s)
- Protocol Development
- Resources
- Delivery
Building Trial Portfolio

• Collaborations/ colleagues

• Cancer Research UK
  • Centre for Drug Development
  • Cancer Research UK centres
    eg Belfast, RMH, GKT, UCH, & Barts

• Pharmaceutical/ Biotech

• ECMC network
  • Collaborative alliance (Astra Zeneca, other)

• Other networks
<table>
<thead>
<tr>
<th>Trial Name</th>
<th>PI</th>
<th>Agent(s)</th>
<th>Investigational drug target(s)</th>
<th>Population</th>
<th>Trial Type</th>
<th>Company Involved</th>
<th>Sponsor / CTU</th>
<th>Phase</th>
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<td>Pacey</td>
<td>Vandetanib + Selomatinib</td>
<td>EGFR / VEGF + MEK</td>
<td>Advanced solid tumours</td>
<td>Investigator-initiated, collaboration</td>
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<td>NOTCH</td>
<td>Jodrell</td>
<td>MK0752 + gemcitabine</td>
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<td>IMCg100</td>
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<td>Jefferies</td>
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<td>ToTem</td>
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<td>Bard</td>
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<td>Cormie</td>
<td>SGI-110</td>
<td>Methylation</td>
<td>Platinum resistant ovarian cancer</td>
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<td>Weekly paclitaxel + AZD014</td>
<td>mTORC1/2</td>
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<td>PakT</td>
<td>Bard</td>
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<td>Advanced triple-negative breast cancer</td>
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<td>ADIPEG-20, pemetrexed and</td>
<td>Arginine metabolism</td>
<td>AS5 negative solid tumours, including mesotheloma +NSCLC</td>
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<td>Calibrate</td>
<td>Bard / Pacey</td>
<td>Tumour and ctDNA profiling for patients on early phase trials</td>
<td>Biomarker</td>
<td>Patients on early phase clinical trials</td>
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### Portfolio

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<tr>
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- High proportion investigator initiated studies
- Developed collaborations nationally and internationally
- Increasing number of first in man/first in class studies
### Year one: in one slide

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<tr>
<th>EPCTT</th>
<th>Urology</th>
<th>CR-UK CI</th>
<th>Academic projects</th>
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</table>
| **OPEN TRIALS:**
- VANSEL-1
- ToTem (set up)
- AT13387 (set up)
| **PROSTATE:**
- High risk men pre surgery
- Linked to imaging, metabolism & lab pathways (ER stress now included)
| **Neal Group:**
- window concept
- AZ collaboration
- Aki + taxane (DJ )
| **TNFR2, 180k grant**
- ctDNA/ molecular characterisation
- PhD supervision
- ER stress |
| **CONCEPTS:**
- ADIPEG20 + pem/cis (PS/Polaris)
- ArQule – Akt i | | | |

**External collaborations:**
- Astra Zeneca, Seattle (RJ)- ctDNA

**Seminar series**
- Anglia research meeting
- DDU advisory board
- Anglian prostate r/ group (VG)

**Trial methodology course for ACF**
- Onc R&D, CTU
- CTU Management Committee
## Combined (Academic/ NHS) Job Plan:

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<th>Day</th>
<th>AM</th>
<th>PM</th>
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<tr>
<td>Monday</td>
<td>Academic/ research</td>
<td>14.00 – 15.30 Urology MDT</td>
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<td>15.30 - 16.00 EPCTT Training updates (alt weeks)</td>
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<td>Tuesday</td>
<td>08.30 X ray Meeting</td>
<td>13.15 – 14.00 Oncology R&amp;D/ preparation for R&amp;D alt weeks</td>
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<td>09.30 – 12 Departmental Meetings</td>
<td>14.30 Fellows education/ trial methodology</td>
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<td>12 – 13.00 CRI Seminar Series</td>
<td>Academic/ Research</td>
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<td>Wednesday</td>
<td>09 – 13.00 EPCTT OPD</td>
<td>Audit/ clinical management &amp; administration</td>
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<td>Thursday</td>
<td>09 – 12.30 EPCTT CIW/ CRF (OPD)</td>
<td>13.30 - 17.30 Urology Trials OPD</td>
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<td>Friday</td>
<td>09.30 – 10.30 PDDG Lab meeting</td>
<td>Academic/ research</td>
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<td>10.30 – 11.30 Project meeting</td>
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<td>11.30 – 12.00 Trial coordinator</td>
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“what do you actually do in the academic time”
Delivery

Timing:
45% of pharmaceutical-led projects completed on time
32% of non-commercial studies,
24% of projects led by other commercial organisations

Budget:
68% of pharmaceutical-led projects completed on budget,
64% of non-commercial studies
48% of projects led by other commercial organisations

Quality

Uni Warwick online data
Delivery

- Plan for Growth 2011
- Benchmark < 70 days from valid application to FPFV
- Future NIHR funding linked

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<th>TABLE SUMMARY - TOTAL FOR ALL 51 PUBLISHED PROVIDERS</th>
<th>Adjusted Trials Total</th>
<th>Adjusted Trials Meeting the Benchmark</th>
<th>% of Adjusted Trials Meeting the Benchmark</th>
<th>Adjusted Trials Not Meeting the Benchmark</th>
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<td>7</td>
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<td>90</td>
<td>59</td>
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<td>30</td>
<td>78.9%</td>
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<td>52</td>
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<td>Cumbria Partnership NHS Foundation Trust</td>
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<td>100.0%</td>
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<td>Great Ormond Street Hospital for Children NHS Foundation Trust</td>
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<td>#</td>
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<tr>
<td>Imperial College Healthcare NHS Trust</td>
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<td>50.0%</td>
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<td>Kings College Hospital NHS Foundation Trust</td>
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<td>59.1%</td>
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<td>Leeds Community Healthcare NHS Trust</td>
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<td>4</td>
<td>66.6%</td>
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<tr>
<td>Leeds Teaching Hospitals NHS Trust</td>
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<td>49</td>
<td>62.0%</td>
<td>30</td>
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<td>Manchester Mental Health and Social Care Trust</td>
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<td>2</td>
<td>66.7%</td>
<td>1</td>
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<td>80.0%</td>
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<tr>
<td>North Bristol NHS Trust</td>
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<td>14</td>
<td>73.7%</td>
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## Setting up a study:

### TRUST R&D DOCS

- All current Trial documentation
  - Protocol
  - Localised:
    - Patient Information Sheets
    - Consent Forms
    - GP Letter
- IRAS documentation
  - NHS REC Form
  - NHS R&D Form
  - Draft NHS SSI Form – list of Depts.
- Approvals
  - REC
  - MHRA
- Personnel Documentation - CV/GCP
  - Draft Contracts (if non-commercial, if Commercial these go direct to Priya usually in advance)
  - Any other documentation e.g. Insurance Certificates, Sponsor Letters
- SSI Authorisations
  - One per Dept from which assistance is required, Trial Name and REC number to be added to each form, including:
    - Cancer Division and Radiation Protection where Radiology involvement
    - Others
  - Documentation to be sent:
    - Protocol
    - Patient Information Sheet
    - Draft SSI Form
    - Authorisation Form (shared drive)
    - REC Form
    - Lab Manual – Tissue Bank Only
- CCTC needs to record the date the authorisations were sent out and the date they were returned (EPIC)

### Other Forms

- Lab Registration Form (generates):
  - Reference Ranges
  - Lab Accreditations
  - Lab Director CV
  - Lab Orders
- ACRC Application Form
- Site Information Form (SiF) Commercial Trials Only
- ARSAC Application Form / PET Proforma for PET/CT
- CRN Application for Service Support Costs

### SPONSOR DOCUMENTS eg

- Finance Disclosure Forms
- Data Protection Consents
- FDA1572
- Delegation Log
- Training Log
- Supply all personnel CV’s & GCP
What is your “Unique selling point?”

**unique**

/adjuːni:k/ <br>

adjective <br>
1. being the only one of its kind; unlike anything else. <br>"the situation was unique in British politics" <br>synonyms: distinctive, individual, special, especial, idiosyncratic, quirky, eccentric, isolated. More

noun archaic <br>
1. a unique person or thing. <br>"some of Lamb’s writings were so memorably beautiful as to be uniques in their class"
Academic Career - Advice 1:

- **Stamina** - perseverance in the face of countless rejections...

- **Papers** - focus on getting papers. Be realistic - any paper is better than none. No point working on a big project that will realistically take 4 years when funding is for 2 years. But ultimately also include some high risk big projects in your portfolio that will give the big paper before your senior clinician scientist application

- **Get grants** - initially small but build your cv to show a track record

- **Institution and mentor** - 50-80 percent of the scores in your grant are for the environment. Match your project to the institutions strengths or move to one that is strong in your interest
• **Follow your passion** in academic medicine. If you don't have one then don't bother wasting your time! Life's too short..
• Learn to play the **game**
• **Publish** quality not quantity
• **Set up collaborations** with a win-win formula (aim to be first or last on everything you do, but sometimes you may need to be in the middle!)
• Work on a **'wow' project**. If it isn't a wow project reconsider whether academic medicine is for you...
• Find something to do **outside** of academic medicine (take up a sport etc).
• Above all **stay focused**, stay on message, and nail that project!
Academic Career - Advice 3:

• Single biggest thing is to get a clear understanding of what you are expected to deliver eg minimum income from grants, commercial trials, numbers/IF of publications etc.

• With this, how and when your performance will be assessed

• Speak to others who have been the process

• Ensure regular reviews with your boss
Summary (in no particular order):

• Stamina
• Balance career/life
• Publish
• Attract funding/grants
• Collaborate
• Seek advice
• Know your goals (personal/institutional) – continued funding
• Focus
Acknowledgements

Gert Attard
Peter Szlosarek
Deb Sarker

Thanks and questions...?
Cambridge Early Phase Trials Team

**Professor Duncan Jodrell**
Early Phase Trials Lead

**Academic Consultant Physicians**
- Dr Bristi Basu
- Dr Richard Baird
- Dr Simon Pacey

**Clinical Fellows:**
Research (ACCI) wards

**Speciality trainees:**
- Med Oncology
- Joint CR-UK CDD
- Academic Lecturer

**Senior Research Nurse**
Teresa Lockett

**Research Nurses**
(4.5 whole time)

**Early Phase Pharmacist**

**Trial coordinators**

**Data / Lab practioner**

**Data Managers**

**Quality Assurance Manager**
Experimental Therapeutics in Cambridge

Cambridge Early Phase Trials Team, Department of Oncology:
Professor Duncan Jodrell
Dr Bristi Basu, Dr Richard Baird, Dr Simon Pacey
Cambridge Cancer Centre: Achievements To Date

**Strength of Science**
- Average: 1 publication per week in journals with IF > 20

**Partnership with NHS**
- Outcomes across multiple cancers are excellent
- Cancer is a key priority for the NHS Trust next 10 years
- Consistently in top 3 ‘Cancer Networks’ for trial entry

**Recognition**
- NHS Biomedical Research Centre – UK leading
- CRUK ‘Major Centre’ designation (1 of 3 – Oxford, Manchester)
- Cancer a Cambridge University ‘Strategic Initiative’
- International: designated an OECI Comprehensive Cancer Centre
Example translational Group: Urological Cancers

Research team

Urology

Radiology

Oncology

Pathology

Window trial
Functional imaging
Targeted biopsies
Serial sampling
Target popln

NGS
QPCR
IHC
Gene profiling
CTC
PD/PK studies
In vivo modelling