Research plan: where to get help?

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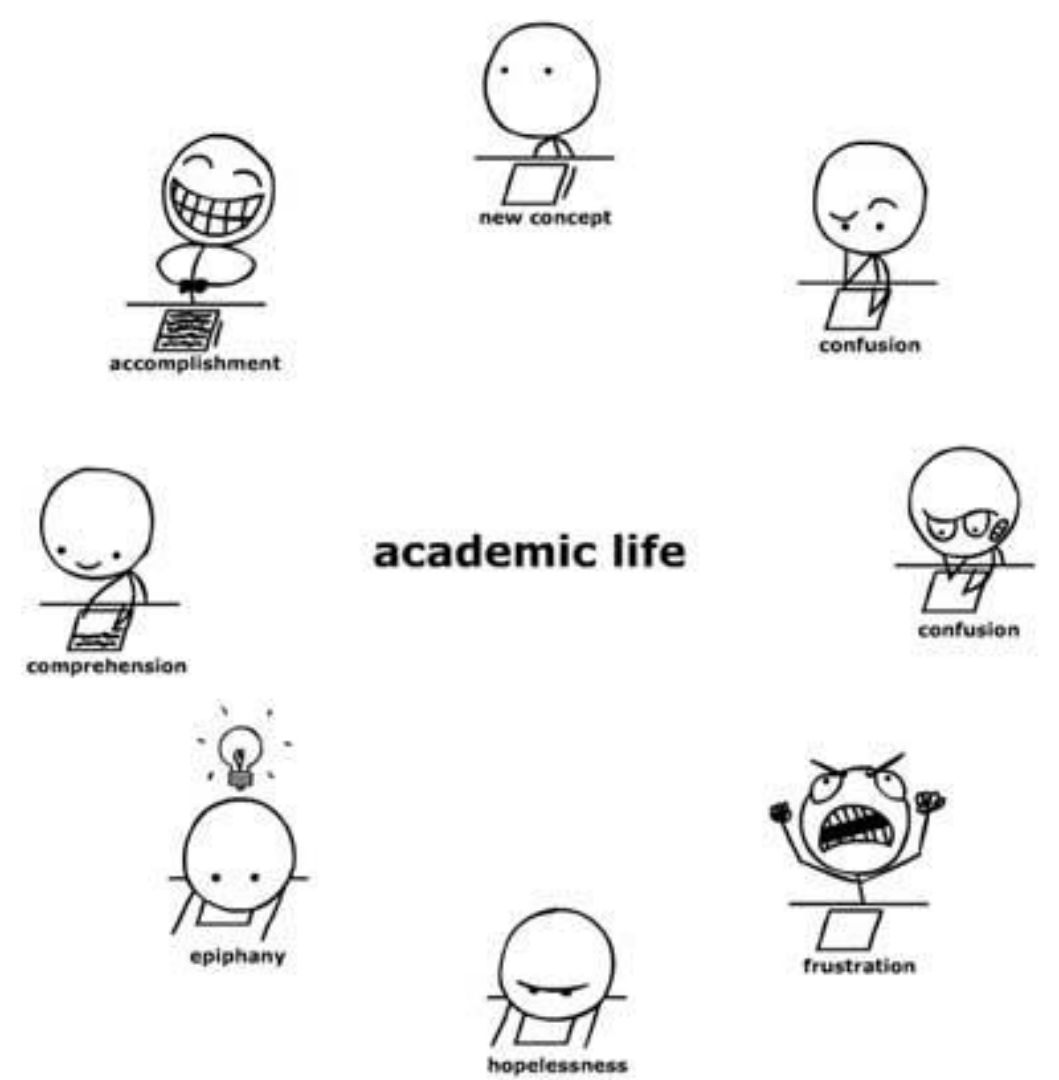
Why do research?



Why do research?

- To reflect on current practice/patient management with a view to improving patient care
- To investigate initial associations seen in your patients
- To develop own skills and/or increase your chances of a new job
- To raise the department's profile or increase opportunities for more income
- To increase opportunities for collaboration
- **Because it's fun and fulfilling!**

The steps of a research project

- Identify research question
- Develop concept sheet
- Conduct pilot study
- Prepare funding application
- Develop study protocol
- Obtain approvals
- Develop analysis plan
- Conduct study
- Analyse data
- Disseminate findings

Topics to be covered

- Identifying a clear research question
- Selecting the right study design
- Dealing with the paperwork
- Disseminating your findings
- Getting your research funded

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What do you want to study?

- Continual evolution in the:
  - practice of medicine
  - drugs available
  - patient population
  - virus
  - disease manifestations
- Always be on the look out for gaps in knowledge
- Read around, attend conferences/meetings, talk to colleagues, monitor novel observations in your patients…
- Start by identifying a broad area that interests you and then home in on a specific research question

Identifying a clear research question

What do you want to study?

My patients are getting older – I'm interested in assessing the affect of ageing on HIV

Far too vague – what aspect of ageing are you specifically interested in?

Well some of them are taking so many drugs –that can't help their adherence to cART

Getting better – what do you mean by 'adherence'…

Identifying a clear research question

- Should have a clear and unambiguous research question before starting to design study
- Think carefully about the **patient population**, the **intervention/exposure** and the **outcome**
- This will allow you to make the most appropriate decisions surrounding the choice of study design, data collection method and the study size
- Question should have clinical/biological relevance

Identifying a clear research question

From this:

What is the effect of ageing on HIV?

To this:

Is there a relationship between the number of non-ARV drugs that an HIV-positive person is receiving for the treatment/prevention of co-morbidities, and his/her self-reported proportion of ARV tablets that are taken at the appropriate time?

Identifying a clear research question

- Read around – make sure your question hasn't already been answered
- Determine if you are able to answer the question:
  - Do you have the financial and laboratory resources?
  - Do you have access to the correct patient population?
  - Do you have the time?
  - Do you have the necessary skills?
- If 'no' to any or all of these, can you collaborate with people who can provide them?
  - Affiliated university researchers?
  - Statistical support?
  - Trust R&D support?
  - PhD student?

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Selecting the right study design

Meta-analyses/systematic reviews of well-designed and conducted studies

Randomised controlled trial (RCT)

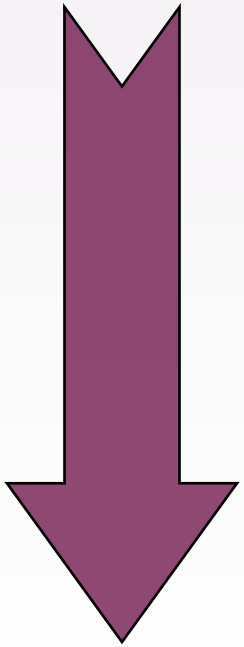
Cohort study
Case-control study

Cross-sectional study

Case series/case note review

‘Expert’ opinion

BEST QUALITY EVIDENCE



WORST QUALITY EVIDENCE

Selecting the right study design

- The research questions that can be addressed in any study will depend on the study design
- Whilst some designs may offer benefits in terms of costs, time and administrative effort, studies that are quick and cheap to perform will generally provide less robust evidence
- Research question SHOULD determine choice of study design
- In practice, lack of time and/or resources usually plays a major part in decision…

Pilot studies

- From Wikipedia…

  …a small scale preliminary study conducted in order to evaluate feasibility, time, cost, adverse events, and effect size (statistical variability) in an attempt to predict an appropriate sample size and improve upon the study design prior to performance of a full-scale research project

- Focus on:
  - Parameter estimates (treatment effect, SD)
  - Feasibility assessment (recruitment rates, barriers to participation, reasons for early drop-out)
  - Pre-test questionnaires
  - Assess reproducibility, etc.

Pilot studies are NOT….

- Small exploratory or descriptive studies
- An excuse to conduct an under-powered study
- A small study that can be done by a student or junior researcher without any funding

Thabane *et al. BMC Medical Research Methodology* 2010, **10**:1
http://www.biomedcentral.com/1471-2288/10/1

BMC
Medical Research Methodology

COMMENTARY Open Access

A tutorial on pilot studies: the what, why and how

Lehana Thabane[1,2*], Jinhui Ma[1,2], Rong Chu[1,2], Ji Cheng[1,2], Afisi Ismaila[1,3], Lorena P Rios[1,2], Reid Robson[3], Marroon Thabane[1,4], Lora Giangregorio[5], Charles H Goldsmith[1,2]

Research or audit?

NHS
Health Research Authority

Defining Research

NRES guidance to help you decide if your project requires review by a Research Ethics Committee

National Research Ethics Service

The National Research Ethics Service (NRES) reviews research proposals to protect the rights and safety of research participants and enables ethical research which is of potential benefit to science and society.

Defining research – guidance from NRES

The purpose of this leaflet is to help you decide if a project is research, which normally requires review by a Research Ethics Committee (REC), or whether it is some other activity such as audit, service evaluation or public health surveillance.

Patients expect health professionals to undertake audit and service evaluation as part of quality assurance. These involve minimal additional risk, burden or intrusion for participants, and are regulated outside of NRES.

Research may involve greater risk, burden or intrusion for participants than standard clinical practice. It may generate conflicts of interest for the researcher, which will require review by an ethics committee. With some exceptions, research requires review by a REC.

The table in this leaflet helps to confirm if your activity is research, audit, service evaluation or public health surveillance.

Research or audit?

- Research:
  - **Primary aim:** to derive generalizable new knowledge – to find out what you *should* be doing
  - **Principal mode of dissemination:** research presentations and/or publications
  - **Target audience:** wider clinical or research community
- Audit/service evaluation:
  - **Primary aim:** to measure *standards* of care; to find out if you *are* doing planned activity and, if so, to assess whether it is working
  - Does not use intervention without a firm basis of support, allocate treatment by *protocol* or *randomisation*
  - **Principal mode of dissemination:** internal reports
  - **Target audience:** colleagues, NHS management

Audit is NOT….

- An excuse to do a study that doesn't require ethics approval

Topics to be covered

- Identifying a clear research question
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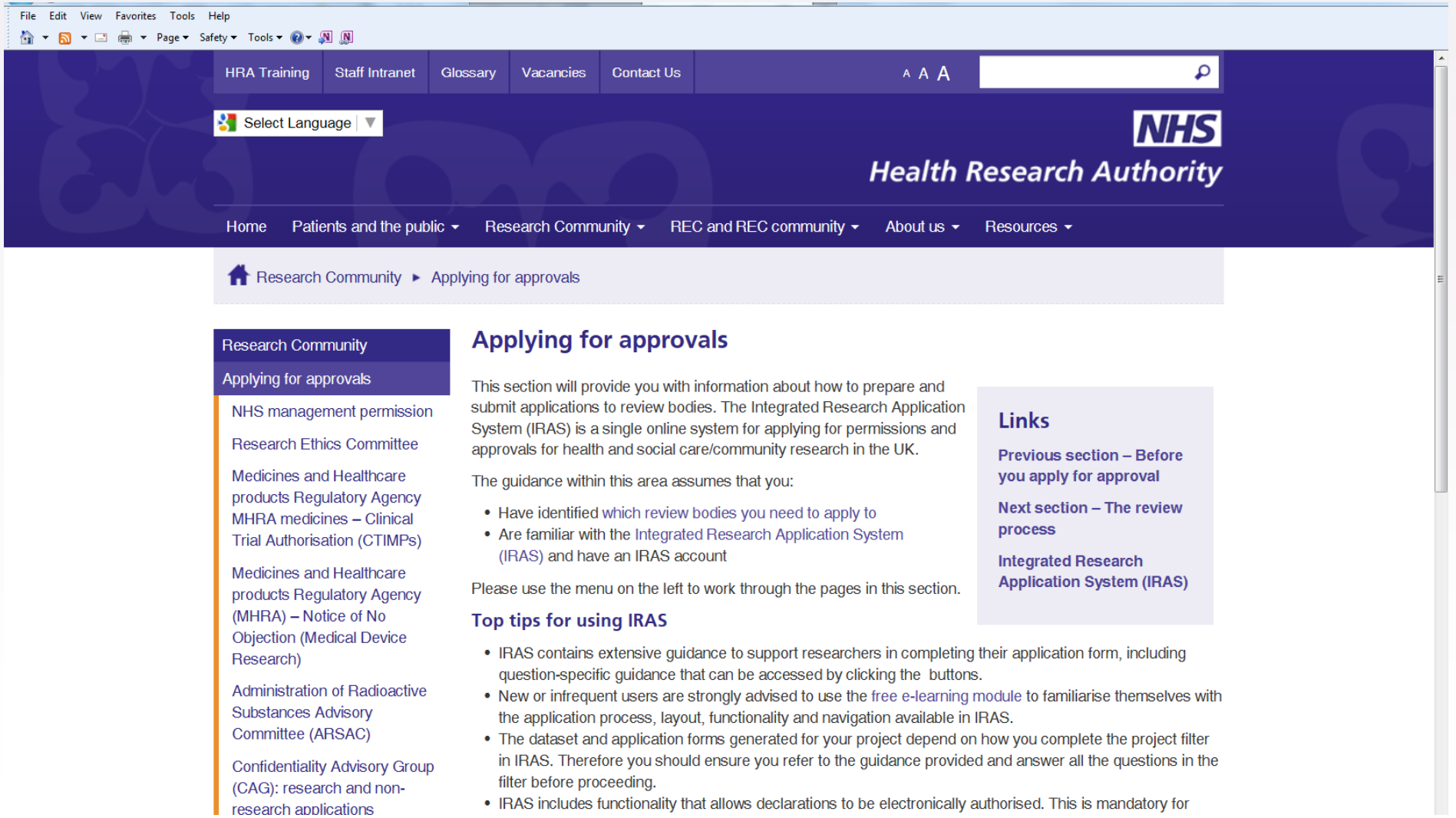
Developing a concept sheet

- Brief document that defines how you will answer your research question
- Can be used for review by all investigators/ sponsors
- Flexible format to allow for modifications at an early stage
- Provides opportunity to establish feasibility
- Helps to identify major defects in study design
- Forms the basis for the study protocol or funding application

Developing a study protocol

- More detailed document which sets out the conditions under which you will conduct research
- Includes information from the concept sheet
- Used for ethics/R&D approval
- After approval, all additional changes constitute amendments:
  - Minor amendments: changes to study team, changes to assessments/fasting requirements
  - Major amendments: changes to major endpoints or length of study
- All amendments require additional ethics approval

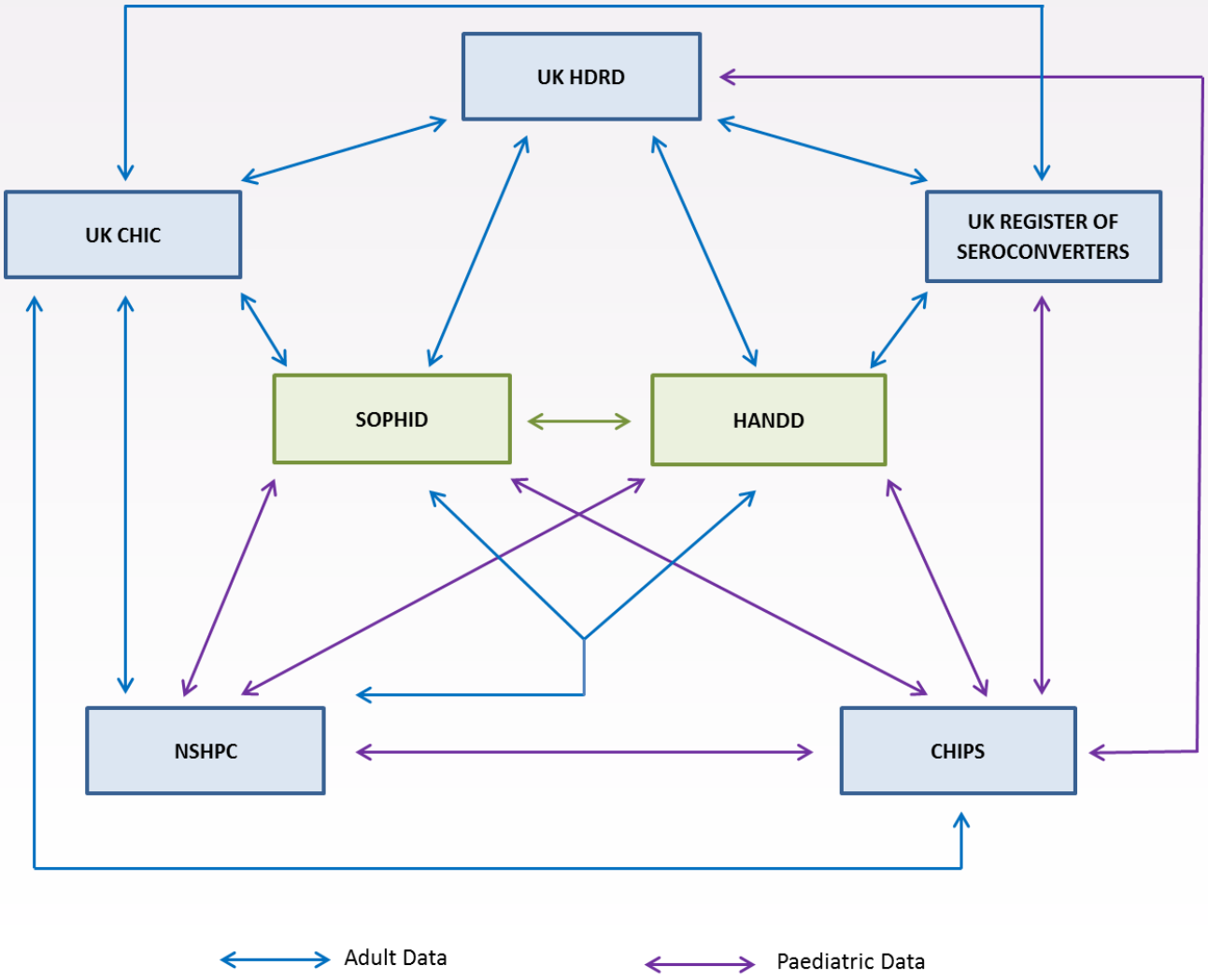
Getting study approvals



Maximising existing resources

- Don’t try to re-invent the wheel – if someone has already collected data, can you use that information?
- Explore opportunities for direct linkage with surveillance and public health databases (e.g. mortality records)
- Linkage with local laboratory services
- Linkage with Pharmacy/drug dispensing databases
- Linkage with disease-specific registers (e.g. cancer registries)

Maximising existing resources



Collaborating with others

- Can be effective way to maximise research outputs
- Be pro-active in searching for opportunities to collaborate
- Develop your own protocol for sharing data
- Ensure that you (and collaborators) have necessary approvals in place to allow for data sharing
- Ensure confidentiality
- Develop clear policy for authorship and any acknowledgements/credits

Topics to be covered

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Writing papers

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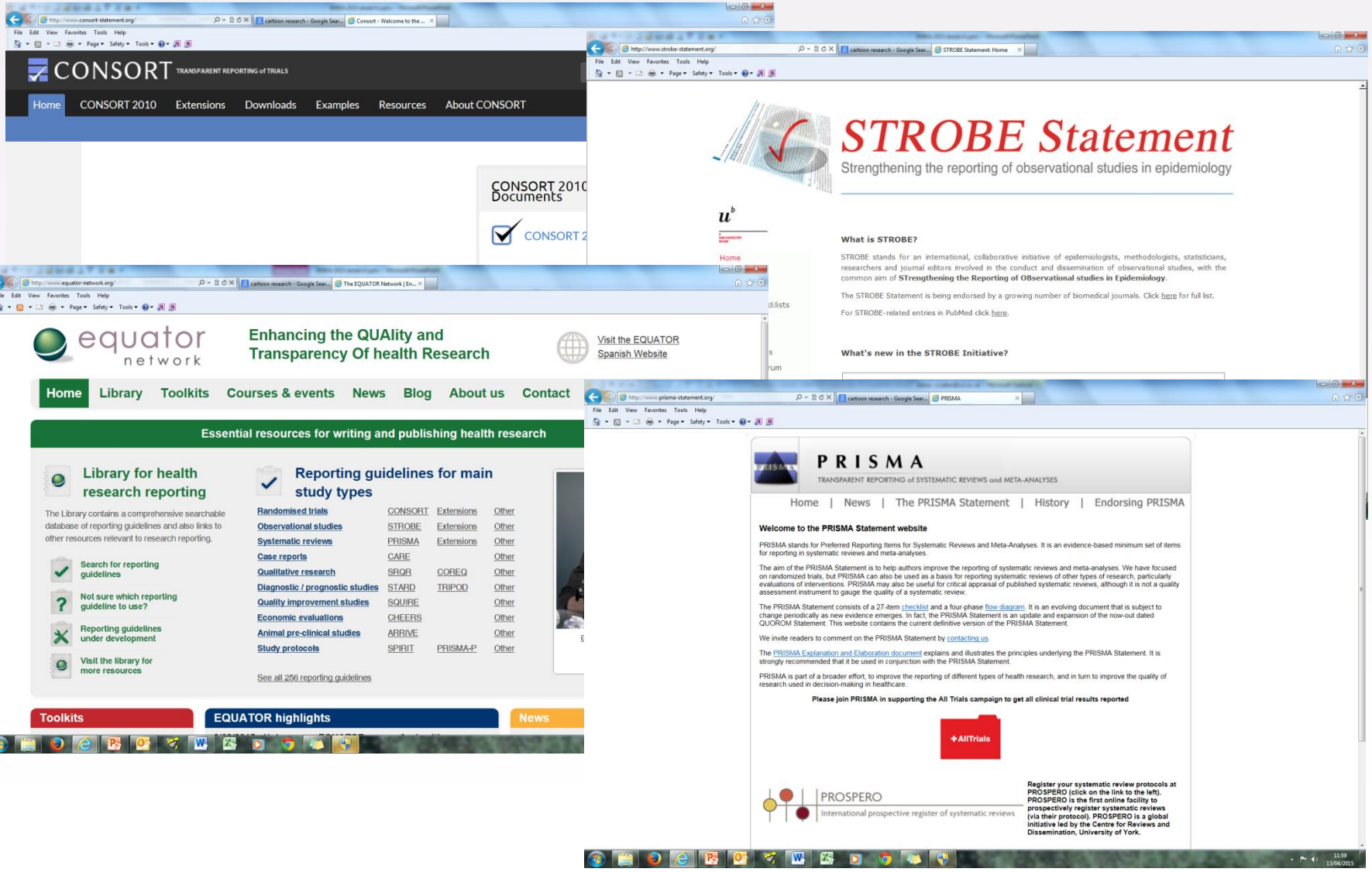
Initial experiences

- Your first paper will…
  - be dreadful
  - take months to write
  - be far too long (aim for <3000 words)
  - be rejected (probably on several occasions)
- You will take the referee's comments personally!
- You will try to work out who the referees are…
- You will be very precious about what you have written
- But it's all good for the soul!

Writing papers



Writing papers

- Abstract: use conference abstract as a template
- Introduction: identify the gap in knowledge, sell its importance, end with aim and/or hypothesis
- Methods: use protocol as template, describe population, recruitment, assessments, statistical methods
- Results: demographics, primary, secondary and any sensitivity analyses
- Discussion: concisely state principal finding(s) and place in context of other work, discuss results in wider context; speculate on potential mechanisms; discuss limitations

Other ways to disseminate your findings

- Publications/posters/oral presentations – expected but may not reach all relevant audiences

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Other ways to disseminate your findings

- How will you ensure that your research findings can be translated into clinical care?
- Who are the key stakeholders in your research?
  - Patient community
  - Academics
  - Clinicians
  - Other healthcare professionals
  - Funders/commissioners
  - Public health professionals
  - Global health leaders
- What are your plans for engaging with each of them outside of the normal academic route?

Other ways to disseminate your findings

- How will you get your research findings out to the HIV community and other audiences (e.g. hospital managers, funders, etc.)
  - Websites (how do people 'find' your website)
  - Study reports
  - Social media
  - Mass media
  - School education

Topics to be covered

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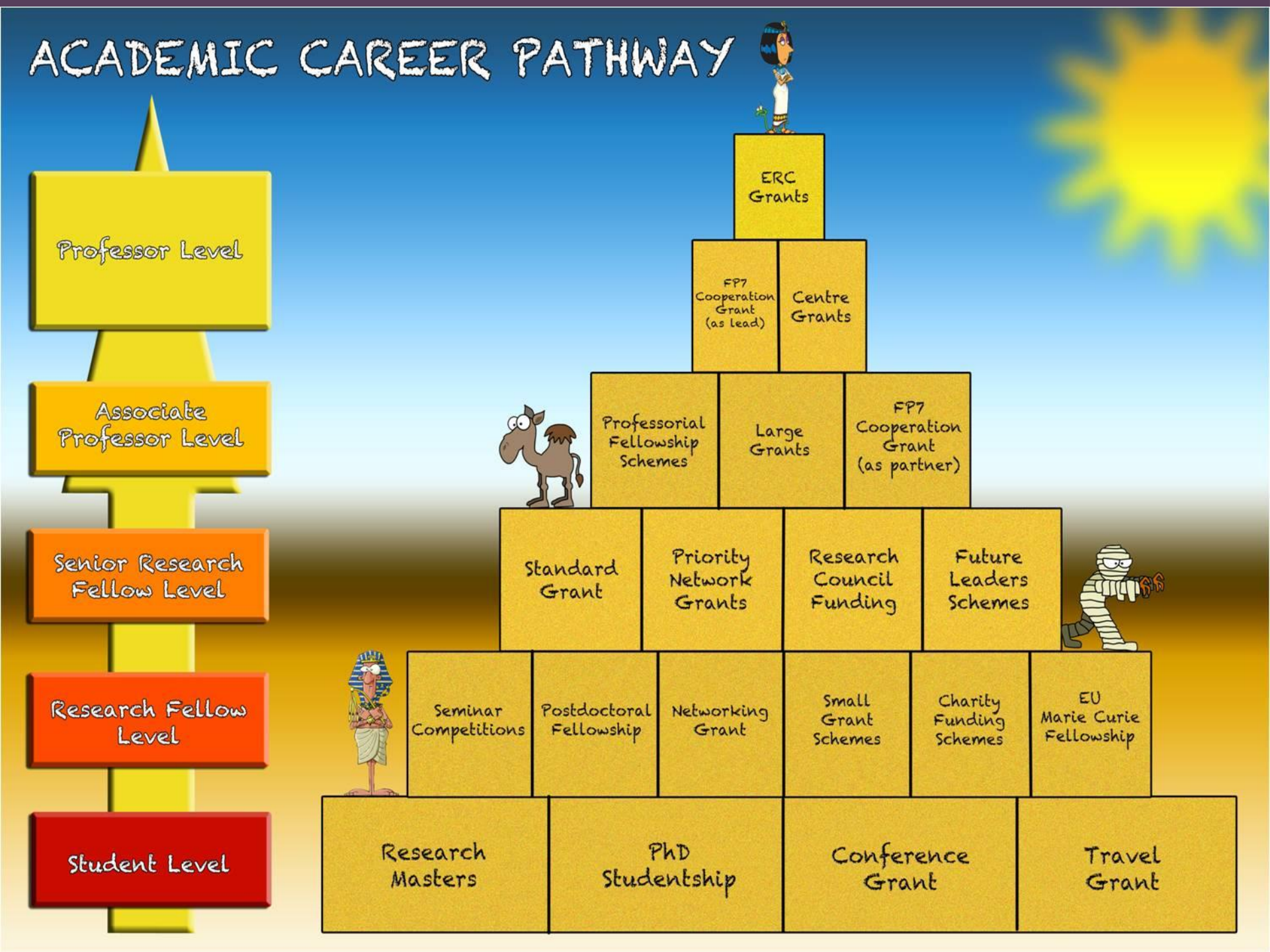
Getting your research funded

ACADEMIC CAREER PATHWAY



Getting your research funded

- Research Councils (www.rcuk.ac.uk)
- National Institute for Health Research (NIHR)
- Wellcome Trust
- European Union
- Charities/BHIVA
- Academic institutions
- NHS Trusts/CLRN funding
- Pharmaceutical companies

Pharmaceutical company/charity funding

- Useful sources of funding for new researchers and/or small projects – may help in development of CV (to give a good track record)
- Often limited in terms of budget
- Charities may not pay 'full economic costs' or overheads; often viewed negatively by universities
- In contrast, universities may charge high rate of overheads for grants from pharmaceutical industry

BHIVA Research Awards

- Competitive scheme, open to all BHIVA members
- Research projects that impact on the improvement of clinical care and management of PLWH in the UK
- Awards of £10K/project; one bigger award (£30K) in 2015
- Applications considered on merit and relevance to BHIVA objectives
- Applications from persons not yet independent researchers or who do not hold an established academic or clinical post are particularly welcomed

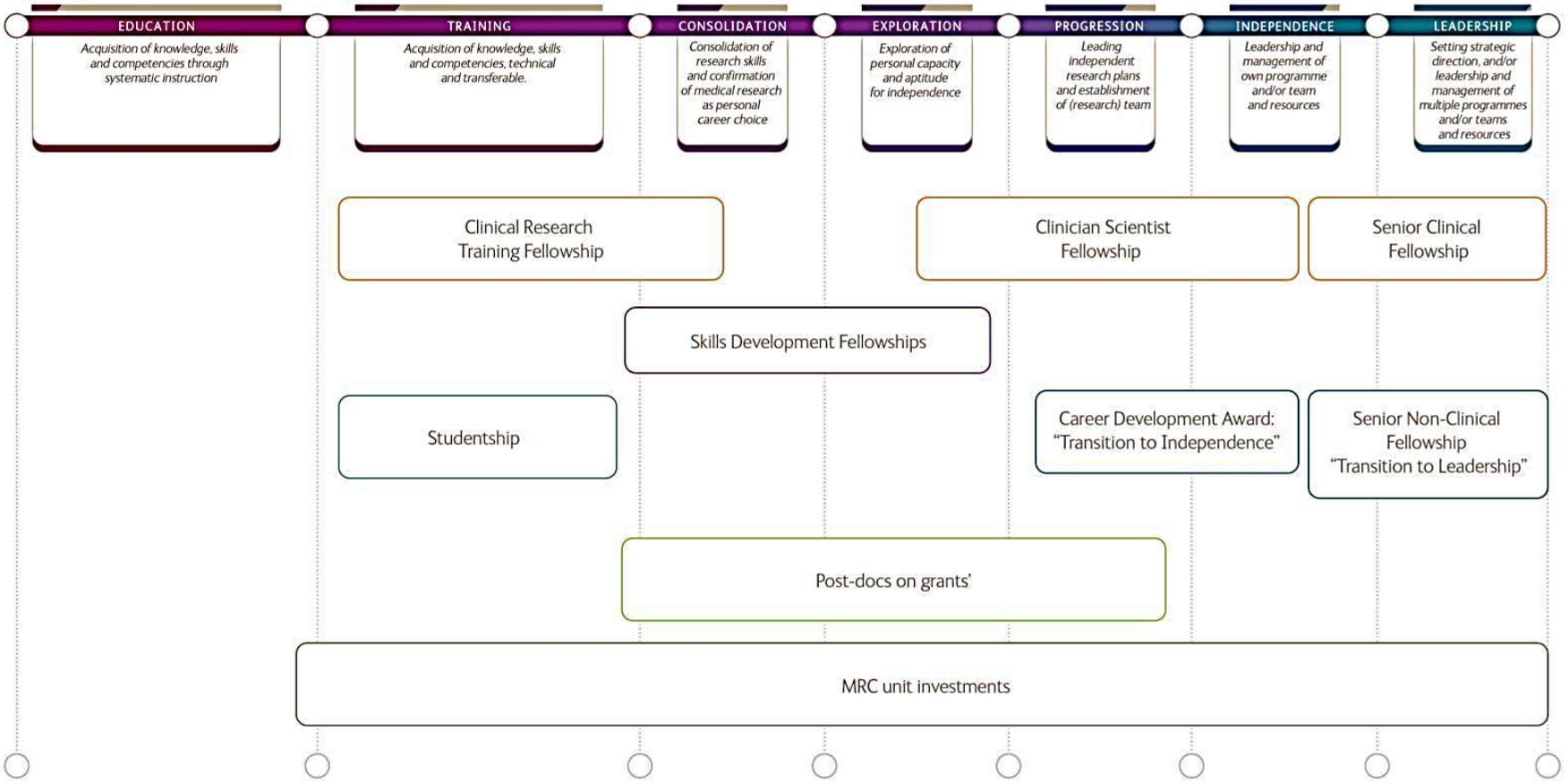
MRC

- Promote research into all areas of medical and related sciences with aims of improving the health and quality of life of UK public, and contributing to wealth of the nation
- Response mode (project/programme) grants
- Strategic initiatives and calls for proposals in specific areas
- Fellowships

www.mrc.ac.uk

MRC

Fellowship schemes



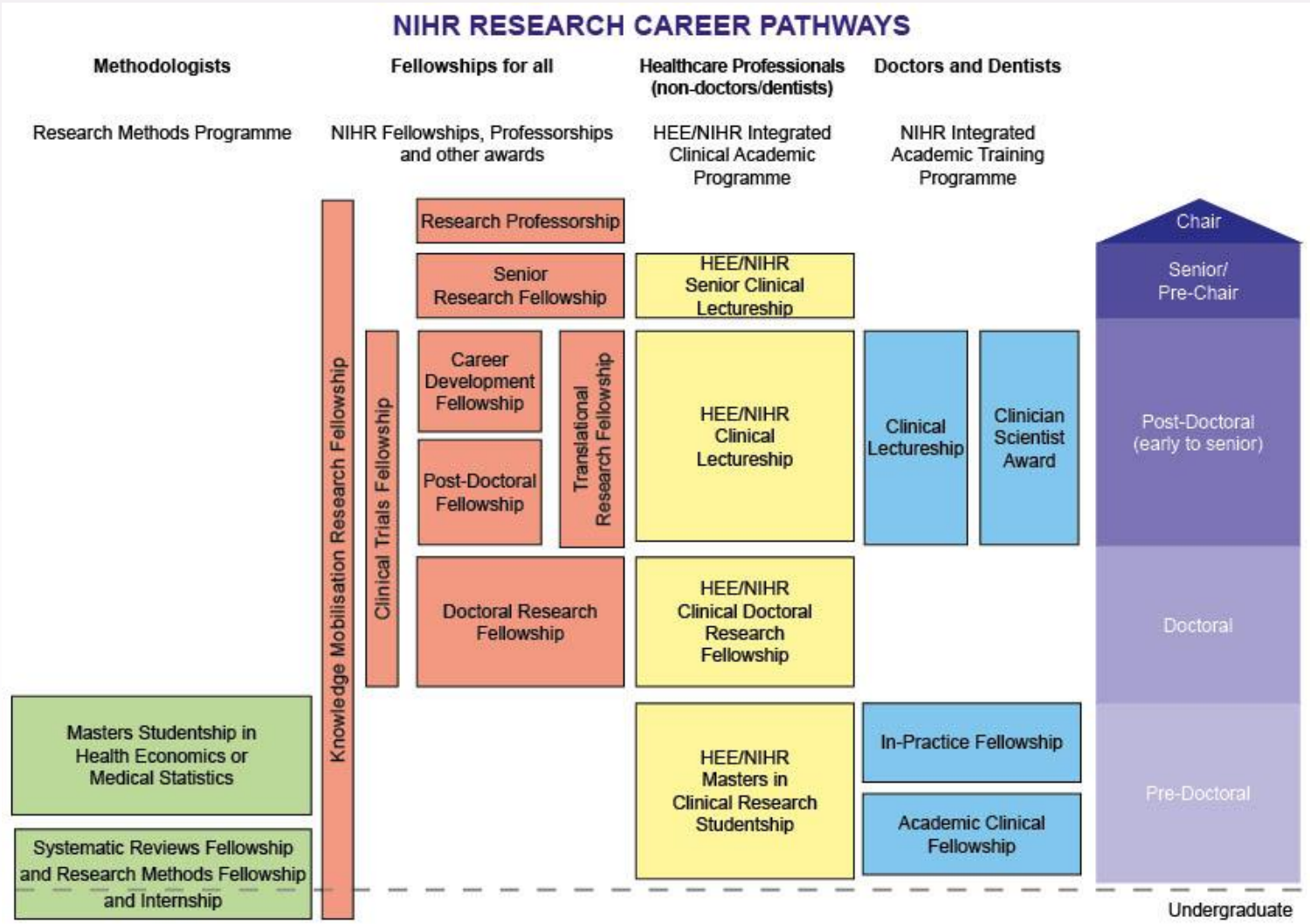
www.mrc.ac.uk

NIHR

- NHS, social care and public health research to support decision making by professionals, policy makers, patients and carers
- Commissioned research and themed calls on specific – calls on specific topics
- Researcher-led research
- Commissioned research and themed calls on specific topics (e.g. Antimicrobial Resistance)
- Training and career development awards

www.nihr.ac.uk

NIHR – training and career development



www.nihr.ac.uk

Steps to becoming an investigator

1. Build up your CV: publications, presentations
2. Develop a broad area of expertise
3. Develop a track record
4. Co-applicant on research grants
5. Seek 'soft' money
   - Scholarships, institutional grants, pharmaceutical funding
6. Fellowship or new investigator grants
7. Project grants/large pharma awards
   - Demonstrate ability to supervise (MD / PhD)
   - Develop collaborations / establish research team
8. Programme grants

Preparing a grant application

- Read the guidance notes carefully
- Is this funding call really suited to me, at my stage of career?
- Start working on the application as far in advance as is humanly possible (not the night before)
- Think about the panel and who will review the application – pitch the application accordingly
- Allow time for institutional sign-off

Why do grants get rejected?

- Not clear how research will add to what is going on internationally or will lead to health benefits
- Unfocused, over-ambitious project
- Unlikely to answer question
- Inappropriately costed (under- OR over-costed)/doesn't represent good value for money
- Methodology not sufficiently detailed
- Lack of preliminary data/appropriate experience
- Lack of good track record/publication record

Final words

- Research IS fun and fulfilling!
- There are well established processes you can follow that will save you time and effort
- Collaborations can be extremely productive, enjoyable and can lead you in unexpected directions
- Engage with your local R&D offices – they are there to support you
- Good luck!