CAPACITY BUILDING
How do we ensure sustainability post grant?

Jennifer Norman
QA and Project Manager
Division of Clinical Pharmacology
University of Cape Town
Divisional Activities

- **Teaching:**
  - Medical students, Master and PhD students

- **Service:**
  - Clinical Therapeutic Drug Monitoring

- **Drug Information:**
  - Medicines information centre
  - South African Medicine Formulary

- **Medicines control council:**
  - Adverse Drug Reaction Reporting
Clinical pharmacokinetics (TB, HIV, Malaria)
- ACTG/IMPAACT
- EDCTP – European Developing Country Clinical Trial Partnerships
- NIH

Drug discovery and development:
- ADME - in vitro drug candidate screening
- In vitro drug candidate activity screening (*P. falciparum*)
- Pre-clinical PK and efficacy testing of novel compounds (malaria)

Pharmacometrics
- NONMEM population modelling
Analytical Facilities

- **Routine Service Laboratory (SANAS accredited)**
  - 365 day service to the hospital and surrounding areas
  - Routine therapeutic drug monitoring
    - Immunosuppressants – sirolimus, cyclosporine, tacrolimus, everolimus
    - Antiretrovirals – efavirenz, lopinavir, ritonavir, nevirapine
    - Anti-tuberculosis treatments - rifampicin
    - Anti-epileptics
    - Antibiotics
    - Overdoses
• **Analytical Research Laboratory**
  - Specialise in the development and validation of new drug assays
  - Focussing on drug interaction studies, specifically TB and HIV and paediatric questions

• **Staff:**
  - Laboratory Director
  - Analysts
  - Technicians
  - Data analysts
  - Quality Assurance/Project Manager

• **Equipment**
  - LC MS focussed
UNIVERSITY OF CAPE TOWN

Personnel

Laboratories Director

Pharmacokinetic Laboratory Director

Senior Analyst (3)

Analyst (1)
Assistant analyst (2)

Technician (1)

Quality Assurance and Project Management

Data Analyst (1)

Administrator

Sample Manager QA Administrator (1)

Routine Laboratory Manager

Laboratory Technical Officer (4)

Data Clerk
Validated Assays

- **HIV:**
  - Efavirenz, Lopinavir, Ritonavir, Nevirapine, Abacavir, Zidovudine, Stavudine, Lamivudine, Tenofovir, Emtricitabine

- **Tuberculosis:**
  - Bedaquiline + M2, Rifampicin + 25 Desacetylrifampicin, Rifapentine + 25 Desacetylrifapentine, Isoniazid + Acetyl isoniazid, Pyrazinamide, Ethambutol, Ethionamide, Gatifloxacin, Moxifloxacin, Ofloxacin, Levofloxacin, Linezolid, Rifabutin + Desacetyl rifabutin, PAS

- **Malaria:**
  - Lumefantrine + desbutyl lumefantrine, Artemether, Dihydroartemisinin, Chloroquine, Amodiaquine + desethylamodiaquine, Mefloquine + Carboxymefloquine

- **Other:**
  - Sulfamethoxazole, Trimethoprim, Progesterone, DMPA
Multiplex Assays
Small volume = Small participant load

Novel sampling = Dried blood spots
Surveillance Studies (compliance, treatment coverage)
Pharmacokinetic application?

Multiplex dried blood spot assay which can assay for ZDV, ABC, STV, LMV, NVP, EFV in 50µl whole blood spot

PRO: EASE OF SAMPLING, RESOURCE POOR SETTINGS, NO ULTRALOW STORAGE, ELECTRICITY SUPPLY, SAFETY, SHIPPING, SUPPLIES
CON: SITE TRAINING, SAMPLING PROCEDURE, PROVISION OF FILTER PAPER, PUNCHING VS. WHOLE SPOT, RIGOROUS STABILITY TESTING REQUIRED PRE-STUDY
The Pharmacology Laboratory

TECHNOLOGY
- Service engineers
- Spares
- Columns
- Solvents

KNOWLEDGE
- Publications
- Texts
- Developmental assistance

Physical

Virtual
Digital Sharing – Knowledge transfer

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**Articles**

**This Week in Global Health (TWiGH) – Dr Greg Martin**
*by THE EDITORIAL TEAM*

We have recently obtained permission to share some very interesting videos on The Global Health Network. The videos are from Global Health Videos by Greg Martin. You can follow more...

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**Introducing: Seeding Labs**
*by EDITORIAL TEAM*

Seeding Labs is an initiative that helps scientists in developing countries to conduct research. For scientists in low and middle income countries, starting a modern lab comes with expenses...

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**Manual of Basic Techniques for a Health Laboratory**
*by ASTRID EISER*

I would like to introduce a very useful and pragmatic guide book for setting up, equipping and running a health laboratory, called Manual of Basic Techniques for a Health Laboratory, ...

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**News**

Harnessing the digital sharing revolution to improve research capacity in African laboratories

Global Health Laboratories panel seminar at the ASLM2014

The Global Health Network will be launching GlobalHealthLaboratories.org at the ASLM2014. We will hold a panel discussion with regional laboratory experts highlighting the role of digital sharing in creating equity of access to research skills and enabling capacity building in...

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**ASLM2014**

Second international conference of ASLM

The conference theme is “Innovation and Integration of Laboratory and Clinical Systems: Reshaping the Future of HIV, Tuberculosis (TB), Malaria, Influenza, Neglected Tropical Diseases and Emerging Pathogens in Africa.”

ASLM2014 will be held in Cape Town, South Africa, on 30...

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**Research Investments in Global Health**

*Resil is an analysis of investments in infectious disease research. Resil has collected data from funders to see what research has been carried out specifically in infectious diseases in the UK.*

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**PROFESSIONAL MEMBERSHIP SCHEME**

Build your professional profile, develop your CV and track your career development as you progress through your career in clinical research.

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**SiteFinder**

FACILITATING PARTNERSHIPS

A free, open-access tool to link research sites with collaborators planning research.

Find a research partner now.

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**eLEARNING**

High quality and certified online learning and training tools to provide a wide range of clinical research.

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**• Laboratory Accreditation**

**• Standard methods**

**• Regulatory training**

**• Online Forums**

- Collegiality
- Troubleshooting
- Supplier networks

**• Off-site QA?**
Capacity building scenario (PK)

Scenario:
- Student arrives at the division for a PhD.
- Develops an assay on LC MS/MS over > 1 year.
- Samples generated by a clinical trial are analysed.
- Student hand in thesis and graduates with a PhD.
- OPTION A:
  - Student returns to their home country to transfer the technology
  - HPLC requires on site maintenance
  - No FSE available on site for the next three months...
- OPTION B:
  - Student is tempted overseas to a well-equipped laboratory, tasking their highly valued technical expertise with them
Main Stumbling Blocks post Capacity Building

- Little insight by the “trainer” into the obstacles facing the resource poor setting
- Unidirectional training only
  - Academic training remains the focus with little attention to the technical side
- Technical support accessibility issues
  - Regional service agent – no local options
- Chemical supply and cost
Recommendations

- Focussed *technical* training during internships
  - Produce “on site FSEs”
- Bi-directional training
  - Training in highly technical labs FOLLOWED by
  - Assistance in the set up of the laboratory *on-site*
  - Assist in the development of *key partnerships* in the supply chain
- Engage with key suppliers
  - Develop a mechanism for the consistent and regular supply of critical consumables and reagents
Mentorship in the Digital Age

- Society for Quality Assurance
- Mentor-Mentee relationships
- Strict application process
- Members only benefit
- Pairings by experts according to fields of expertise, location and experience
- Year-long professional relationship with an individual
- Interactions via email, Skype