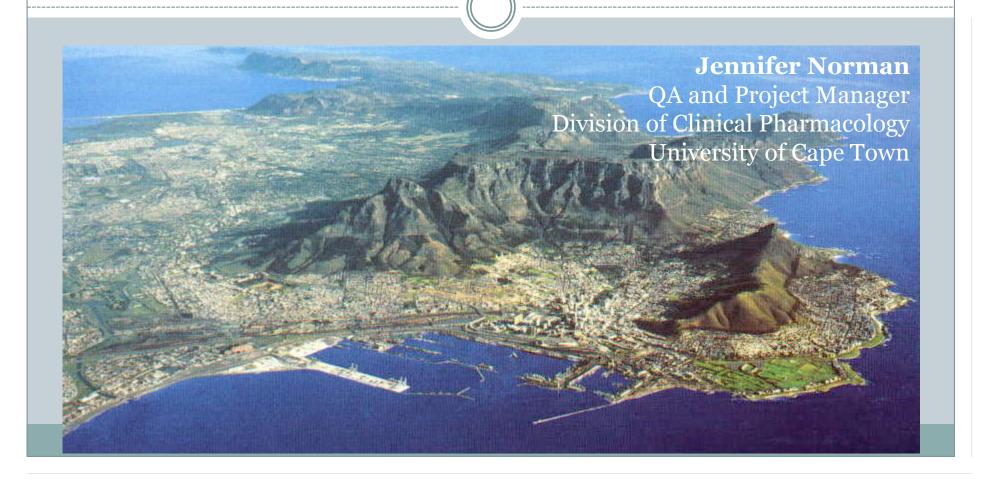


CAPACITY BUILDING How do we ensure sustainability post grant?





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





Research Focus

- Clinical pharmacokinetics (TB, HIV, Malaria)
 - o ACTG/IMPAACT
 - EDCTP European Developing Country Clinical Trial Partnerships
 - o NIH
- Drug discovery and development:
 - o 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



- o 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





Facilities cont.



- 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





Personnel



Laboratories Director

Pharmacokinetic Laboratory Director

Quality Assurance and Project Management

Routine Laboratory Manager

Senior Analyst (3)

Data Analyst (1)

Sample Manager QA Administrator (1)

Laboratory Technical Officer (4)

Analyst (1)
Assistant analyst (2)

Administrator

Data Clerk

Technician (1)





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 + Desacetylrifabutin,
 PAS

• Malaria:

Lumefantrine + desbutyl lumefantrine, Artemether,
 Dihydroartemisinin, Chloroquine, Amodiaquine +
 desethylamodiaquine, Mefloquine + Carboxymefloquine



• Other:

Sulfamethoxazole, Trimethoprim, Progesterone, DMPA



Developmental focus

- Multiplex Assays
- Small volume = Small participant load

IMPAACT

- 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

Physical

KNOWLEDGE

- Publications
- Texts
- Developmental assistance

Virtual

Digital Sharing – Knowledge transfer

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 ...

Introducing: Seeding Labs

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 ...

Manual of Basic Techniques for a Health Laboratory by ASTRID ERBER

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, ...

FEATURED



Understanding the principles of Good Clinical Laboratory Practices (GCLP) - Training presentations

by KAWUONDO, KARLA LAM

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 ... READ MORE

ASIM2014

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 ... READ MORE

Research Investments in Global Health



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

PROFESSIONAL MEMBERSHIP

SCHEME

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sites with collaborators planning research.

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eLEARNING

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

- 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.
- o 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:

x 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
 - o Regional service agent no local options
- Chemical supply and cost



Recommendations

- Focussed <u>technical</u> training during internships
 - o Produce "on site FSEs"
- Bi-directional training
 - o 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