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Clinical Pharmacology Registrar Training Program

Welcome to the Division of Clinical Pharmacology. We hope that you will find your 4 years of training rewarding. This summary will orientate you as to what is expected from you during the next 4 years.

To become a registered Clinical Pharmacologist, you have to be accepted as a Fellow of the College of Clinical Pharmacologists of South Africa by the College of Medicine of South Africa [FCCP(SA)] and obtain your Master of Medicine in Clinical Pharmacology (MMed) from the University of Stellenbosch.

During the next 4 years we will provide you with a fully accredited training programme to become a Clinical Pharmacologist. To successfully complete this programme, you should meet the following requirements at the end of each year:

Activity	Year 1				Year 2				Year 3				Year 4			
	3	6	9	12	3	6	9	12	3	6	9	12	3	6	9	12
FCCP Part 1 exam																
FCCP Part 2 exam																
Research assignment																
4-monthly portfolio review																

FCCP (SA)

To obtain the FCCP (SA) you have to pass two exams: the Part I focuses on the basic science of clinical pharmacology and the Part II on the clinical aspects of clinical pharmacology and therapeutics. You are eligible to write the Part I exam after you have completed 15 months of your registrar time; and Part II after you have completed 3 years of your registrar time. Please visit the College of Medicine of South Africa (CMSA) website (www.collegemedsa.ac.za) for more details on the requirements as well as the curriculum. You have to complete a portfolio that is downloadable from the website. The portfolio will be reviewed by the College to determine your eligibility to participate in the Part II exam. The completion of your portfolio is a continuous process until you have successfully passed the Part II exam. The portfolio will be reviewed every 4 months

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by your mentor in the Division of Clinical Pharmacology to determine your progress. This may include an evaluation (written or oral) at the end of every 4-month rotation.

Basic course work modules
The Division of Clinical Pharmacology offers short courses in the field of Pharmaceutical Medicine. The Faculty of Medicine Health Sciences and the Department of Medicine offers courses on research methodology, GCP, ethics and epidemiology/statistics. We expect that you participate in these programmes to assist you with the preparation for the Part I and Part II exams.

Research assignment
You have to submit a research assignment relevant to the field of Clinical Pharmacology as part of the requirements to be awarded the MMed in Clinical Pharmacology.

The process

- You will find the relevant requirements for the MMed dissertation in the most recent Faculty Yearbook. Please familiarise yourself with the document *Stellenbosch University, Faculty of Medicine and Health Sciences, Provisions for Research Assignments of Structured Master's Program*.
- Identify a project and study leader and sign a contract with your study supervisor, clearly setting out time lines and responsibilities. Start early and stick to deadlines. A completed project is a prerequisite (Stellenbosch University candidates) for registration for the FCCP part 2 exam.
- Do a preliminary literature search and discuss the feasibility of your proposed project with your study leader and various experienced researchers.
- Prepare a protocol and apply for ethics approval from the HREC. For more information visit the following webpage: http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Health-Research-Ethics.aspx
- Finish data collection timeously.
- Prepare a dissertation (approx. 80 pages). Several revisions are often required. The dissertation should be handed in by your supervisor to the chairman of the postgraduate committee (with an accompanying cover letter).
- The postgraduate committee will appoint one internal and one external examiner. The dissertations (first draft handed in to the postgraduate committee) will be graded, and changes may be suggested. These changes should be addressed in the final (second) version – only then will the marks be captured (i.e. the research component is only considered complete when the second (or more) version is found to be acceptable by the postgraduate committee).
- You will give an oral presentation on completion of the research assignment, and you are expected to publish the research project in an accredited peer-reviewed journal.

Time frame

- We suggest that you discuss and plan your project with your supervisor in your first year of training and perform the study and write-up your findings in your 3rd year. The dissertation (as stated above) has to be handed in prior to registration for the final exam.

Assistance from the Department/Faculty

- In an attempt to assist registrars, all students will be expected to complete the *Short course on Research Methodology* which is a 12 weeks (once a week) course provided by the Departement of Medicine every year.
- Visit the University Stellenbosch website at www.sun.ac.za/international/pgskills for various courses which may help you with specific areas of your research.
- The Registrar Research Support Office has excellent resources and courses to facilitate your MMed project. It is available at: http://www.sun.ac.za/english/faculty/healthsciences/rdsd/registrar-research/Pages/default.aspx
- The research protocol must be presented to and approved by the relevant Faculty Committee and by the Health Research Ethics Committee before commencement.

Overtime

You will be expected to participate in the on-call roster for the Clinical Pharmacology service of the hospital, including after-hours duties in the Casualties Unit. You will also be expected to participate in after-hours duties in the Poisons Information Centre (PIC). During your medicine rotation you will be expected to participate in your firm's intake and post-intake duties. You will also need to set aside time at weekends for self-directed learning and development of training material, as well as for reading journals.

Clinical Pharmacologist on-call responsibilities:

- To respond to medicine related queries from hospital colleagues including:
  - advice on rational selection of medicine
  - dosing in special populations (obesity, renal impairment, liver impairment, pregnancy, lactation, paediatrics, giving drugs via NGT etc)
  - adverse drug reaction assessment
  - polypharmacy with potentially multiple drug-drug interactions
  - assist to fast-track urgent Pharmacy & Therapeutic Committee requests
- To assist the Clinical Pharmacology laboratory (see below)
- Therapeutic drug monitoring (TDM) interpretation
- To act as the clinical consultant for the PIC as needed. PIC will take the calls first and refer when a clinical opinion is required.

Assisting the Clinical Pharmacology laboratory will entail you visiting the TDM laboratory at least twice a day in the morning and again at around 15h00. Your duties will be to review abnormal laboratory results and contact clinicians as required. Please make sure that you are familiar with the various aspects of TDM and how it impacts on the work of a Clinical Pharmacologist. You will be expected to understand the aspects of a good laboratory practice relevant to the TDM laboratory and its day-to-day functions.

Casualties on-call duties:

After-hours duties will involve seeing and treating patients in the medical Emergency Unit as part of the first-line team, with referrals to other specialties as necessary. You will be expected to see and manage a wide range of presenting complaints, but it is encouraged that you focus on presentations strongly related to Clinical Pharmacology and Therapeutics, e.g. poisoning and overdose, adverse drug reactions, etc.

PIC on-call responsibilities:

This will consist of weekdays after hour calls (16h30 through 08h30) and weekend (08h30 through 08h30) calls to advice on toxicology related queries. You will be provided with electronic

references and the information databases to manage the calls. You will be on call with a consultant who will be available to assist you with complicated cases.

Medicine rotation responsibilities:
During your medicine rotation (4 – 8 months of your 4 year training) you will function as a member of the team and participate in overtime. You will admit patients during intake and participate in the post-intake ward round.

Ward consultations

The registrar on call is responsible for managing all the consultations. On a Monday during the 09:30 registrar meeting arrangements will be made to allocate a registrar to review the Clinical Pharmacology consultations in the hospital which may include:

- polypharmacy with potentially multiple drug-drug interactions
    - advice on rational selection of medicine in this context
- dosing in special populations (obesity, renal impairment, liver impairment, pregnancy, lactation, paediatrics, giving drugs via NGT etc)
- adverse drug reaction (ADR) assessment
- toxicology consultations
    - advice on management of toxic ingestions of medicines

Registrars are responsible for presenting cases during the weekly Grand Ward Round in Clinical Pharmacology. The focus will be therapeutics preferably next to the patient bed side.

Medical student teaching and training
You will be expected to assist with the teaching of medical students. The teaching will consist of didactic lectures and student orientated ward rounds. As far as possible, we will allocate lectures that align with your stage of training. Every year you will be allocated new teaching topics to allow you to cover a broad range of topics. You are expected to attend the lectures of the senior pharmacology staff when you start your time in Clinical Pharmacology and before you take over a lecture from a colleague. Before you teach a topic for the first time, a senior lecturer must review the prepared contents.

The ward rounds will stimulate the teaching of Clinical Pharmacology around the bedside. Registrars and/or pharmacology lecturers will facilitate the student ward rounds. You will be expected to participate in at least 1 of these ward rounds weekly. The selected ward round case will be focused to consolidate student knowledge and understanding.

Registrar teaching
Interactive discussions will take place between you and the academic staff of the Division on a regular basis during journal clubs and patient case discussions. Peer teaching through presentations and discussions with registrars and consultants from other universities' Clinical Pharmacology units will occur on Mondays at 13:00.

Clinical work
Clinical patient care will form 25% of your training. During the first year of your rotation, you will spend dedicated time attached to a medical firm with 4-monthly rotations. You are required to plan your rotations at the end of each year for the following year. Note that the College expects you to undertake the following rotations as a minimum:
At least 2 months' rotation is each of the following: intensive care unit, paediatrics or adult medical casualty/emergency department, primary health care clinics run by the Department of Family Medicine or equivalent.

At least 2 months' rotation in at least 4 of the following: endocrinology, dermatology, neurology, rheumatology, gastroenterology, infectious diseases, including HIV care, cardiology, oncology, psychiatry, anaesthesia, including pain clinic, pulmonology, nephrology, geriatrics.

Journal club
You are expected to present a journal article on a regular basis at the Journal Club of the pharmacology postgraduate students. Pre-part I registrars are expected to present articles from focused clinical pharmacology journals such as *The British Journal of Clinical Pharmacology* and *Clinical Pharmacology and Therapeutics.* Pre-part II registrars will focus more on general medicine journals such as *The Lancet* and *The New England Journal of Medicine.*

Pharmaceutical and Therapeutic Committee (PTC)
Part of your training will be to participate in the Tygerberg Hospital PTC meetings. You will be required to assist with the assessment of motivations for formulary inclusion as feasible. PTC functions will also form part of your on-call duties.

Clinical trials
As part of your training, you will actively participate in clinical trials performed by the Winelands Rheumatology Centre in Stellenbosch under supervision of Prof Reuter.

Ethical review of clinical trials
You will once a month review the ethics submission for a clinical trial on behalf of the Health Research Ethics Committee (HREC), assessing both the scientific merits of the study and ethical aspects. You will review the clinical drug trial submissions with the support of a Clinical Pharmacologist. This will allow you to develop an appreciation for the ethical conduct of clinical trials as well as insights into Good Clinical Practice (GCP).

Department of Medicine activities
The Division of Clinical Pharmacology forms part of the Department of Medicine. You are expected to attend the Monday morning Department Meeting and the Thursday afternoon Academic Meeting. You will be expected to present cases from time to time on a rotational basis at the Academic Meeting.

The basic lay out of your work week will be as follows:

	Monday	Tuesday	Wednesday	Thursday	Friday
08:00					
08:30	Toxicology case discussions				Clin Pharm Journal Club
09:30	Registrar meeting				
10:00					
11:00					
12:00			MBChB III tut		
13:00	Registrar teaching			Combined ID Journal Club	
14:00				Divisional Staff or Research Meeting	
15:00					
15:30				Dpt of Medicine Academic Meeting	
17:00					

Text books and prescribed reading

The reading of journal articles forms a critical basis for life-long learning and evidenced based decision making. It is essential that journal reading becomes part of your professional life. Registrars are advised to study the following text books and leading medical/clinical pharmacology journals:

Text books (latest editions):

- Katzung, BG. Basic & Clinical Pharmacology. Lange
- Goodman and Gilman's. The Pharmacological Basis of Therapeutics. McGraw Hill
- Walley T et al. Pharmacoeconomics. Churchill Livingstone
- Strom BL. Pharmacoepidemiology. John Wiley
- South African Medicines Formulary (SAMF).
- Straus S et al. Evidence-Based Medicine: How to Practice and Teach EBM. Churchill Livingstone
- JP Griffin, J O'Grady, Textbook of Pharmaceutical Medicine. Blackwell
- B Spilker, Guide to Drug Development: A Comprehensive Review and Assessment. Lippincott Williams Wilkins

Reviews and seminal articles in leading medical and pharmacology journals, such as:

- New England Journal of Medicine
- Lancet
- Pharmacological Reviews
- Clinical Pharmacology & Therapeutics
- Annual Review of Pharmacology & Toxicology
- Drug Safety
- Annals of Pharmacotherapy

Homepages of FDA, EMA, ICH (http://www.fda.gov/; http://www.ema.europa.eu/ema; http://www.ich.org/)

Leave
As per Circular H166/2017, your annual leave should be planned and scheduled at the start of an annual leave cycle; i.e. 01 January of each year. At least 10 consecutive working days must be taken at a time. We encourage you to take all your allocated leave during the annual leave cycle: 10 consecutive working days in the first 6 months and 10 consecutive working days in the second 6 months with a few days for long weekends.

Performance evaluation
Your portfolio of learning will be evaluated every 4 months and signed by your supervisors. This forms part of your admission requirements to the part II exam. In addition, your performance will be evaluated every 3 – 6 months as part of the staff performance management system (SPMS) of Tygerberg Hospital. The performance rating scale is as follows:

CATEGORY	VALUE
Unacceptable Performance	1
Performance Not Fully Effective	2
Fully effective	**3**
Performance Significantly Above Expectations	4
Outstanding Performance	5

We expect you to score a 3 for all your Key Performance Areas. A score higher than 3 is exceptional and a performance that exceeds the requirements of a registrar at the specific year of training.

I understand the requirements of the registrar training program.		
Date:	Candidate:	Signature:

We wish you lots of success with your training. We will support you wherever we can, but ultimately you are responsible for your learning. The registrar programme is coordinated by Prof Eric Decloedt and any problems or queries should first be directed to him.

Date last edited: Tygerberg, 02 August 2021

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