

## Advanced Clinical Research Monitoring Interactive Workshop

Program (2-weeks course, 8-19 July 2019)

**Opening Ceremony Summer School 2019 - July 10 - Location: Janskerk**

Date	Time	Activity	Description
Mon 8	Morning	Group discussions Lectures	Why clinical trials? Lifecycle of a clinical trial History of clinical trials
	Afternoon	Lectures	Drug development Trial design
Tue 9	Morning	Lectures	Rules & Regulations Health Technology Assessment
	Afternoon	Lectures	Life of a CRA Sponsors & CROs
Wed 10	Morning	Workshop	Job applications
	Afternoon	Lectures	Investigative site team The trial subjects
Thurs 11	Morning	Workshop Lecture	Ethical reasoning in medicine EC & DMC
	Afternoon	Lecture Workshop	Essential documents & data management Communication
Fri 12	Morning	Lectures	Trial visits Safety assessment
	Afternoon	Lecture	The protocol + study binder
<i>Sat/Sun</i>	<i>Weekend</i>		<i>Leisure time</i>
Mon 15	Morning	Workshop	Monitoring of virtual subject A
	Afternoon	Workshop	Subject A: plenary discussion
Tue 16	Morning	Workshop	Risk based monitoring
	Afternoon	Lecture	IITs + GMP monitoring
Wed 17	Morning	Workshop	Monitoring of virtual subject B
	Afternoon	Lecture Workshop	Compliance Oncology trials
Thurs 18	Morning	Workshop Lecture	Subject B: plenary discussion Medical devices
	Afternoon	Workshop	Drug accountability/reconciliation
Fri 19	Morning	Formative assessment	Formative assessment (theoretical & practical) Evaluation/certification
	Afternoon		<i>Homeward Bound</i>