Contents

Part I  Introduction/Background

1 Studies Linked to the Evolving HIV Epidemic in South Africa: Informing the CAPRISA Scientific Agenda 3
Quarraisha Abdool Karim, Cheryl Baxter and Salim S. Abdool Karim

2 CAPRISA: Establishing a Research Centre to Undertake HIV Clinical Trials 15
Salim S. Abdool Karim, Cheryl Baxter and Quarraisha Abdool Karim

3 Overview of Clinical Trials 27
Anneke Grobler

Part II  CAPRISA Clinical Trials for HIV and HSV-2 Prevention

4 Antiretrovirals for HIV Prevention: The CAPRISA 004 Tenofovir Gel Trial 41
Cheryl Baxter, Leila E. Mansoor, Tanuja N. Gengiah, Salim S. Abdool Karim and Quarraisha Abdool Karim

5 Rolling Out of Tenofovir Gel in Family Planning Clinics: The CAPRISA 008 Implementation Trial 57
Leila E. Mansoor, Kathryn T. Mngadi and Quarraisha Abdool Karim

6 The Impact of Conditional Cash Transfers in Reducing HIV in Adolescent Girls and Boys (RHIVA): The CAPRISA 007 Matched Pair, Cluster Randomised Controlled Trial 77
Hilton Humphries, Ayesha B.M. Kharsany, Kerry Leask, Fanelesibonge Ntombela and Quarraisha Abdool Karim

7 HIV Vaccine and Passive Immunity Trials 91
Nigel Garrett, Kathryn Mngadi, Nivashnee Naicker and Lynn Morris
Part III  CAPRISA Clinical Trials for HIV–TB Treatment

8  CAPRISA 003: Timing of Antiretroviral Initiation in HIV-TB Co-infected Patients—The SAPiT Trial ................................. 107
Nesri Padayatchi, Kogie Naidoo, Andy Gray, Salim S. Abdool Karim and Anneke Grobler

9  Scaling up TB-HIV Integration in Public Health Clinics:
Translating Research Findings into Practice ....................... 121
Kogieleum Naidoo, Santhanalakshmi Gengiah, Nesri Padayatchi and Salim S. Abdool Karim

Part IV  Experiences and Lessons Learnt from Clinical Trials
in CAPRISA

10  From Bench to Bedside: Lessons from HIV Natural History
Cohort Studies .................................................. 137
Carolyn Williamson, Lynn Morris, Nigel Garrett, Penny Moore, Wendy Burgers and Koleka Mlisana

11  Advancing Understanding of HIV Infection in Women
Through Mucosal Immunology Studies ............................. 153
Jo-Ann S. Passmore, Lenine L. Liebenberg, Nonhlanhla N. Mkhize, Derseree Archary and Lindi Masson

Part V  Essential Support Activities for the Conduct of Clinical Trials

12  Good Practices in the Conduct of Clinical Trials: Good
Community, Pharmacy and Laboratory Practices ............... 169
Tanuja N. Gengiah, Natasha Samsunder, Janet A. Frohlich and Fanelesibonge Ntombela

13  Ethical and Legal Considerations for Realising Post-trial
Access of Novel Experimental Interventions: Lessons from
the CAPRISA 004 Trial ........................................ 191
Jerome Amir Singh

14  Grants Management ....................................... 201
Marian Swart, Devenie Latchmananan, Nasrin Amla and Carl Montague

15  Taking Science to the People: CAPRISA Communication
and Media Strategies for Announcing Outcomes of Pivotal
Study Findings ................................................. 209
Smita Maharaj

16  What Does the Future Hold for CAPRISA? .................. 231
Salim S. Abdool Karim, Cheryl Baxter and Quarraisha Abdool Karim

Index .............................................................. 235
The CAPRISA Clinical Trials: HIV Treatment and Prevention
Abdool Karim, S.; Abdool Karim, S.S.; Baxter, C. (Eds.)
2017, VI, 243 p. 24 illus., 23 illus. in color., Hardcover
ISBN: 978-3-319-47517-2