1. **International Center for indigenous Phytotherapy studies (TICIPS) RCTs in South Africa**

**Global Approaches of Integrative Oncology**

T/CAM phytotherapies with *Sutherlandia frutescens* are used in southern Africa for multiple health conditions, including cancers, infections, diabetes, stress, etc. Preclinical studies indicate interactions occur with pathways pertinent oxidative stress, inflammation, immunity, tumorigenesis, lipid and steroid metabolism, etc. As a foundation for clinical studies of efficacy, two RCTs were conducted to: i) assess whether consumption of *S. frutescens* by healthy or HIV infected adults causes adverse events; affects HIV or other infections; alters hematologic, physical or psychological parameters; ii) develop (with the South Africa Medical Research Council (MRC) and Medicines Control Council (MCC))norms for safe and rigorous RCTs of T/CAM phytotherapies; and iii) promote communication and partnerships between allopathic and traditional medical providers.

One trial (1) randomized 12 subjects to a treatment arm of *S. frutescens* (800 mg/bid) and a placebo arm of 13 subjects for 3 months. No significant differences in adverse events or physical, vital blood, and biomarker indices were observed; however, treatment subjects reported improved appetite, as had been reported anecdotally. The second trial (2) used an adaptive two-stage design: In Stage 1, 56 participants were randomized to plant leaf powder (400, 800 or 1,200 mg bid) or placebo for 24 weeks. In Stage 2, 77 additional subjects were randomized to either 1,200 mg bid or placebo. Final analysis included data of 107 participants in both stages. Results: *S. frutescens* did not affect HIV viral load or CD4 T-lymphocyte count; however, mean and total burden of infection was greater in the treatmentarm; and notably to two active tuberculosis cases in subjects taking isoniazid preventive therapy (IPT). The possible interaction between *S. frutescens* and IPT is being evaluated in cell culture and animal studies, and may presage antagonistic interactions with IPT for other botanicals (3).

1. Johnson et al (2007) A randomised, double-blind, placebo-controlled Phase 1 Trial of *Lessertia frutescens* in healthy adults. *PLoS Clinical Trials* 2 : e16. PMC1863514.
2. Wilson et al (2015) Consumption of *Sutherlandia frutescens* by
	1. HIV-seropositive South African adults: an adaptive double-blind randomized placebo controlled trial. *PloS One* 10(7):e0128522. doi: 10.1371/journal.pone.0128522. PMC4506018.
3. Folk et al (2016) Does concurrent use of some botanicals interfere with treatment of tuberculosis? *Neuromolecular Med*. 18: 483-486. doi: 10.1007/s12017-016-8402-1. PMID: 27155670.