



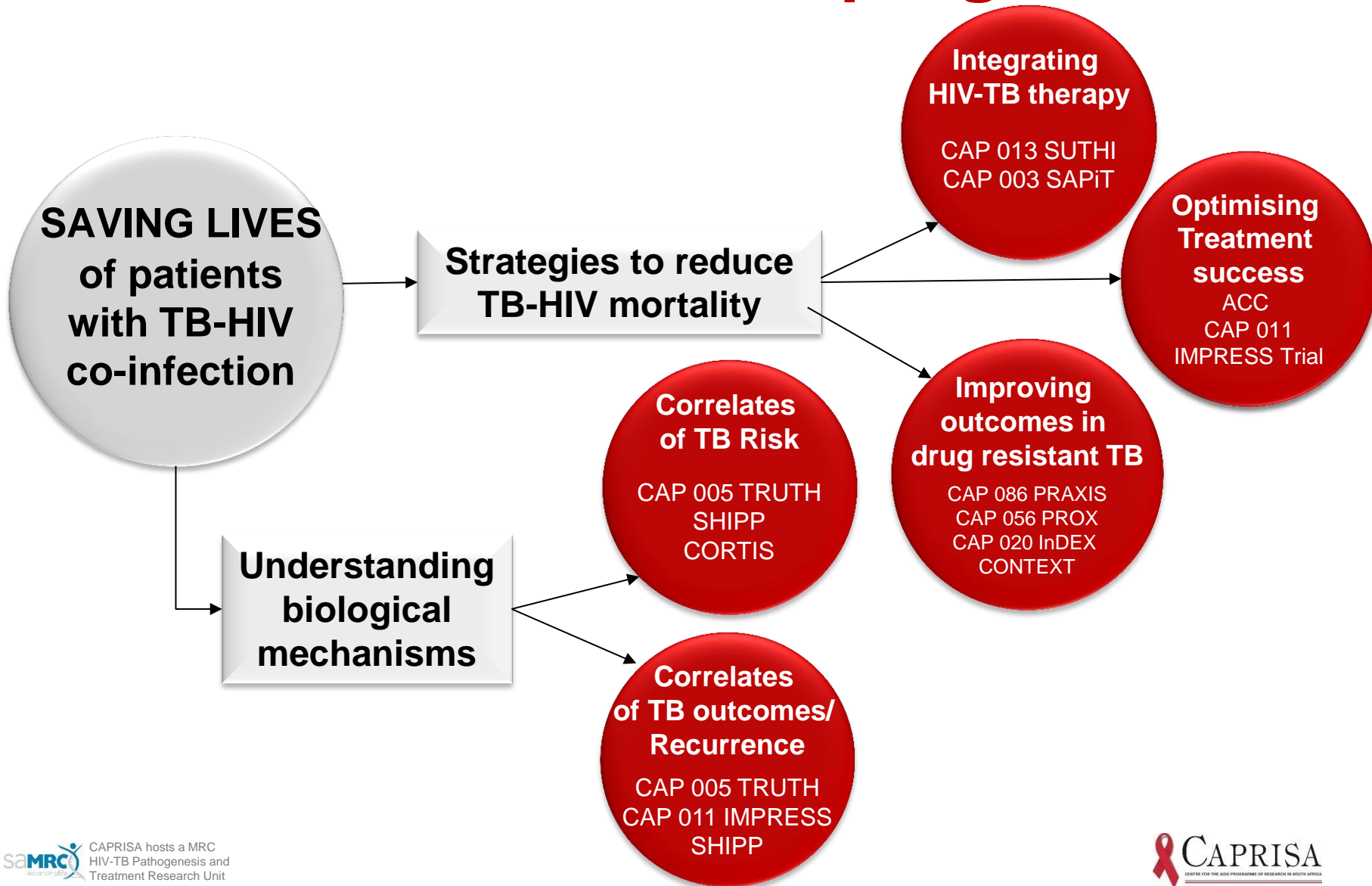
# Overview of TB research output in South Africa and Drug resistant TB clinical trials

*Presented at the Italy-South Africa Bilateral workshop on Transmissible Diseases: HIV/AIDS, Malaria and Tuberculosis, 5 April 2019*

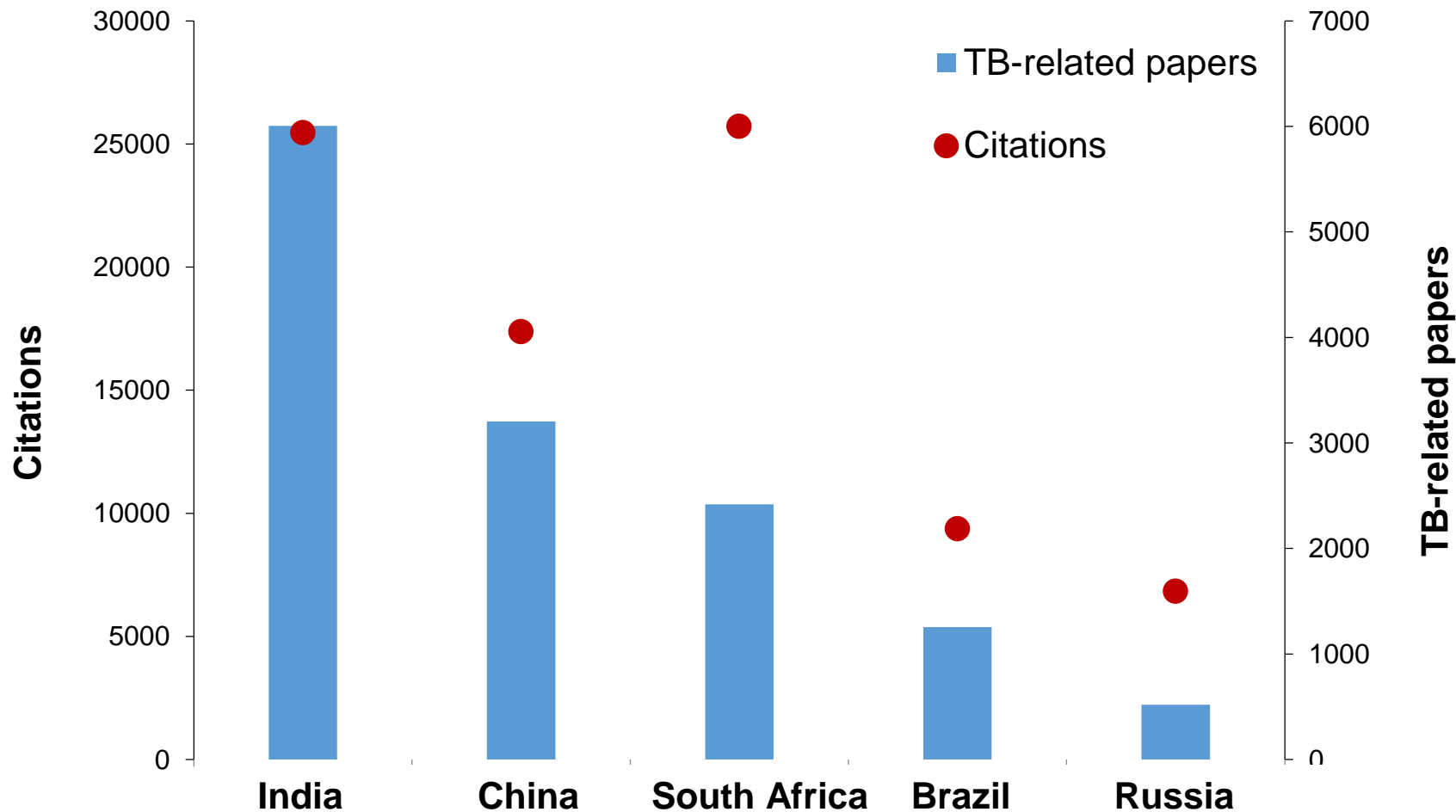
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# 5 components of the CAPRISA TB and HIV clinical research programme

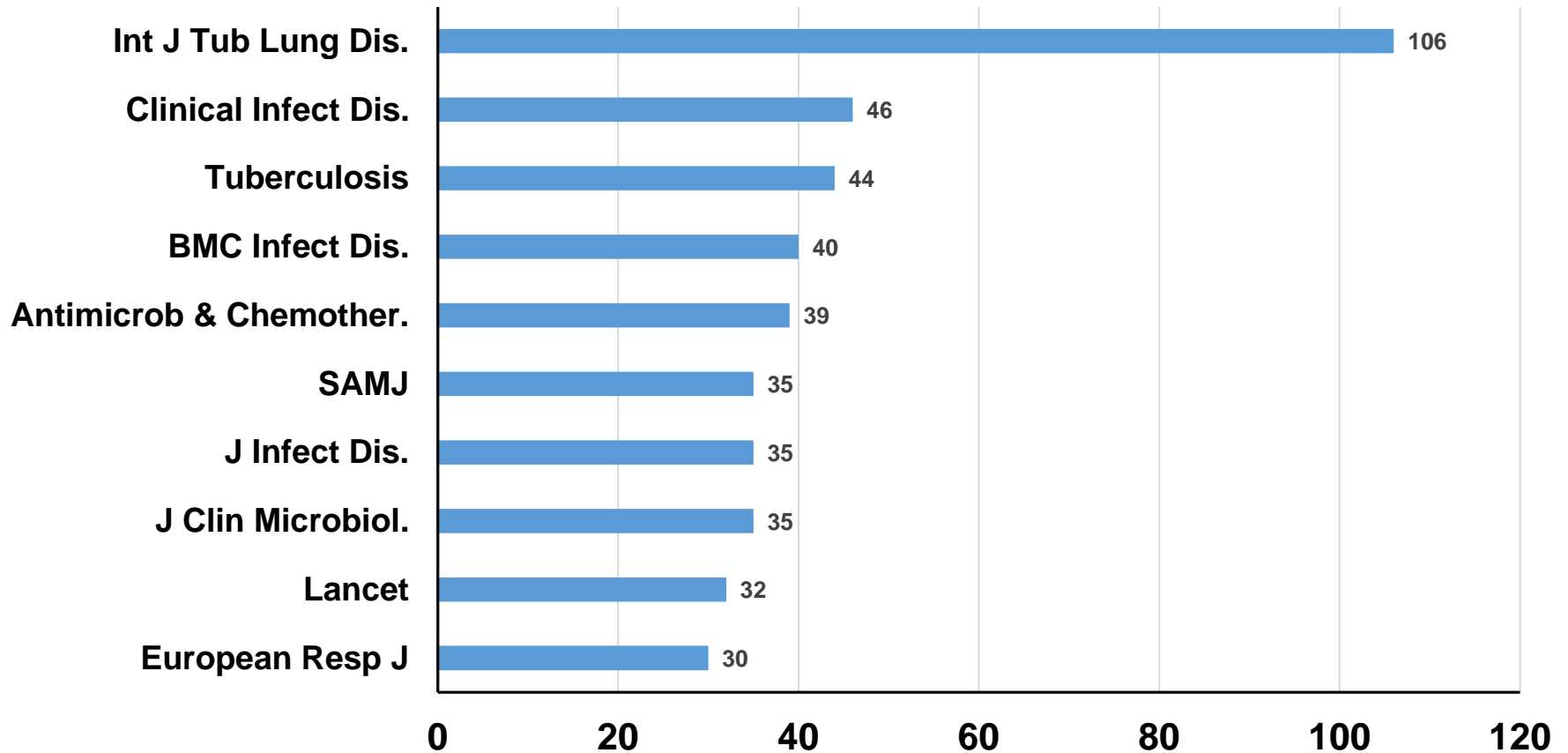


# TB-related publications for BRICS countries: 2013-2017



Source: Scopus, analysis up to 18 January 2018

# South African TB publications by journal: 2013-2017



Source: Scopus, data up to 11 January 2018

# Clinical TB studies in South Africa: 2013 onwards

- **Data from Clinicaltrials.gov on TB trials in South Africa:**
  - **99 studies in last 5 years**
    - 33 phase II or II/III
    - 16 phase I or I/II,
    - 16 phase III,
    - 7 phase IV
    - 27 phase unknown
  - **90% - interventional, 10 % observational**

# 2018 Global TB Drug and Regimen Clinical Research<sup>1</sup>

Ongoing Clinical Development Research: Strategy/Optimization/Regimen Development

## Phase 2

**Bedaquiline-Delamanid** (ACTG 5343)

**Bedaquiline - Pretomanid - Pyrazinamide** (BPaZ) (NC-005)

**Bedaquiline - Pretomanid - Moxifloxacin - Pyrazinamide** (BPaMZ) (NC-005)

**Levofloxacin** with OBR for MDR-TB (OPTI-Q)

**Linezolid** Dose-Ranging

Nitazoxanide

Beta-Lactams

**High Dose Rifampicin** (PANACEA)

TB PRACTECAL - regimens with

**Bedaquiline-Pretomanid-Linezolid**

Known chemical classes are color coded: **fluoroquinolone**, **rifamycin**, **oxazolidinone**, **nitroimidazole**, **diarylquinoline**, **benzothiazinone**, **imidazopyridine amide**.

<sup>1</sup> Strategy trials, regimen development, open label, repurposed drug studies. Details for projects listed can be found at <http://www.newtbdrugs.org/pipeline/clinical>

<sup>2</sup> OBR = Optimized Background Regimen

## Phase 3 Regimens

**Bedaquiline-STREAM** MDR-TB Trial Stage 2 with oral OBR (9 mo) or OBR with injectables (6 mo)

**Bedaquiline-Pretomanid-Linezolid** (NiX-TB)

**Delamanid** with OBR for MDR-TB

**High Dose Rifampicin** for DS-TB (RIFASHORT)

**Rifapentine - Moxifloxacin** for DS-TB (CDC TBTC 31)

**Pretomanid-Moxifloxacin-Pyrazinamide** (STAND)

## Optimization/Post Market

**Bedaquiline-Linezolid** with OBR for MDR-TB (NEXt Trial)

endTB 5-Regimen Trial for MDR TB

PredictTB – PET/CT, biomarkers DS-TB, 4 mo

Clofazimine - formulation development



[www.newtbdrugs.org](http://www.newtbdrugs.org)

Updated: March 2018

# SUMMARY

- South Africa continues to produce high quality research in the field of TB
- The focus of the research is on phase II studies
- Largely in the field of intervention studies involving drugs
- Research Gap is in understanding behaviour