

BJ Medical Clinical Research Site (#31441), Pune, India. Overview

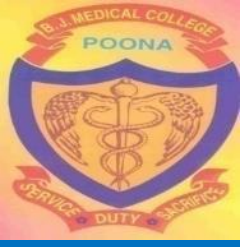


Sadaf Inamdar, (POR)
On behalf of
Nishi Suryavanshi
Clinical Research Site
Coordinator



BJMC Site Hospital: Sassoon General Hospital (SGH)

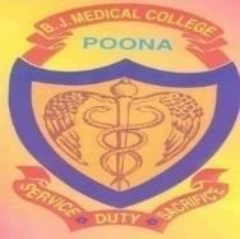
- 1296-bed public hospital
- Provides care to the lower socio-economic community living in and around Pune
- 525,000 outpatient visits per year
- 60,000 hospital admissions per year
- **Largest HIV treatment center in India**
 - >30,000 patients registered (>3000 children)
 - >12,000 patients on treatment (>400 Children)
- Treats 4000 tuberculosis suspects/cases yearly



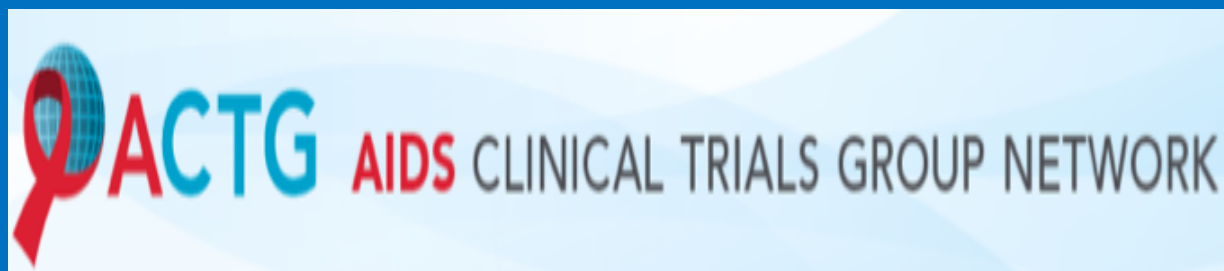
Additional Research Partners

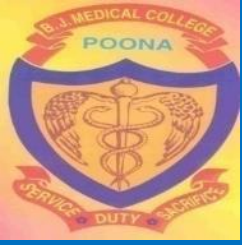


- National AIDS Research Institute (NARI)
- National Institute of Virology
- Pimpri-Chinchwad Municipal Corporation hospitals/clinics
- Pune Municipal Corporation hospitals/ clinics
- KEM Hospital
- Bharati Vidyapeeth Medical College and Hospital
- D. Y. Patil Medical College, Hospital & Research Centre



International network studies



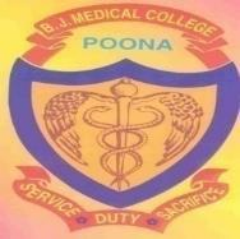


BJGMC

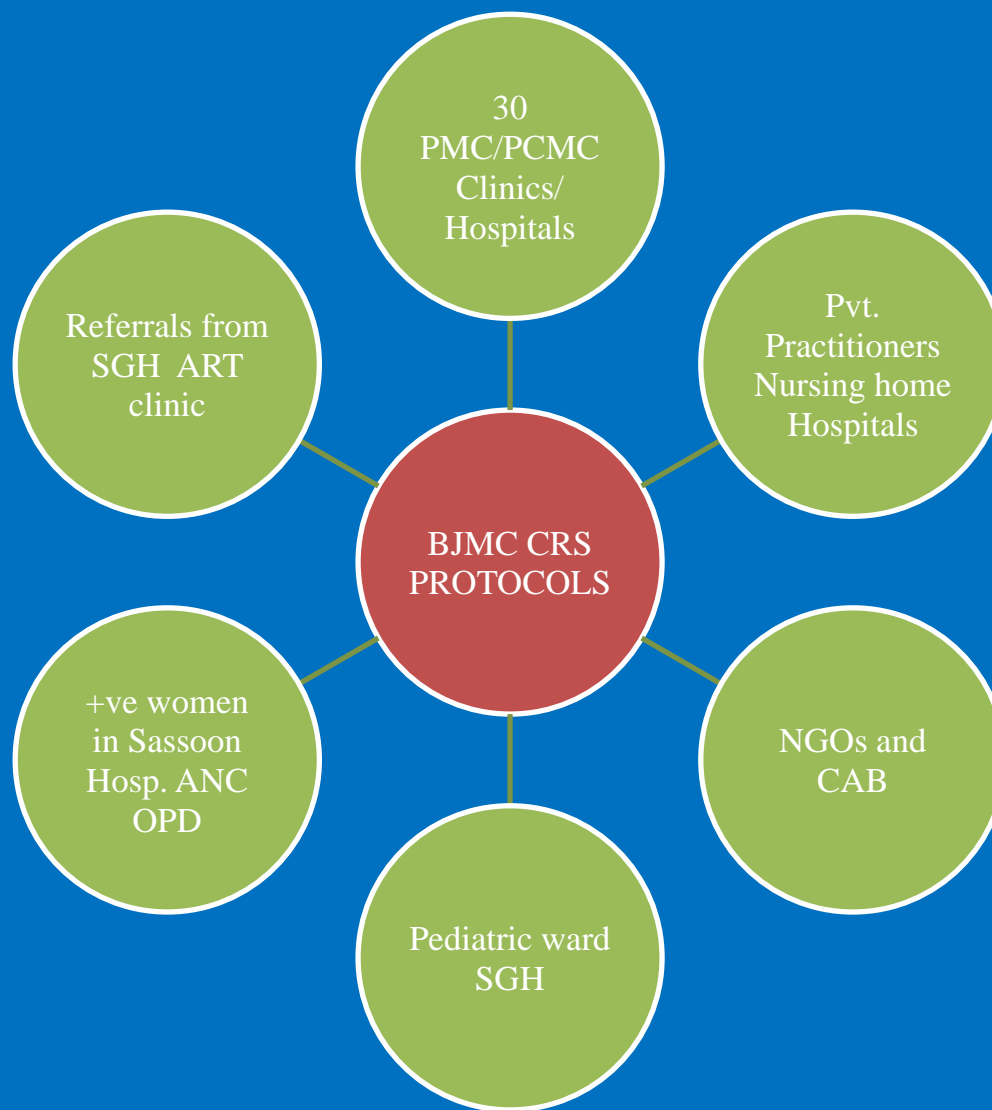
Research Infrastructure

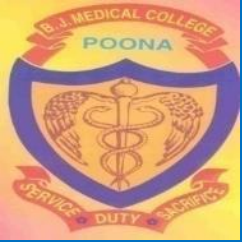


- FWA /DCGI approved Ethics Committee
- Community Advisory Board
- Experienced research team (HSP, GCP, GCLP trained)
- Partnership with 7 BJMC clinical departments
- State-of-the-art laboratories
- Data management center
- Research pharmacy
- Clinical management/counseling units



Potential Participants for Network studies



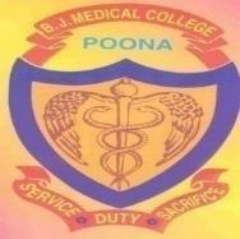


Referrals



Referral Clinics and NGOs:

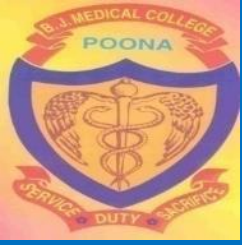
- Provided with general overview of the study by
 - Study and outreach counselors
 - Community and study coordinators
 - Study counselors
 - Clinicians.
- Provided with IRB approved patient handouts and referral slips.
- Outreach counselors visit all PMC/PCMC hospitals, counsel potential participants and accompany them to site hospital.



IMPAACT studies



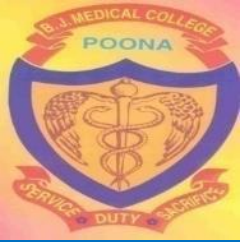
- **Completed:**
 - P1060
 - P1070
 - P1073
 - PROMISE BF+FF
 - PHOENIX feasibility study
- **Ongoing**
 - P1078
- **Upcoming**
 - P1108, P2005 and P2010



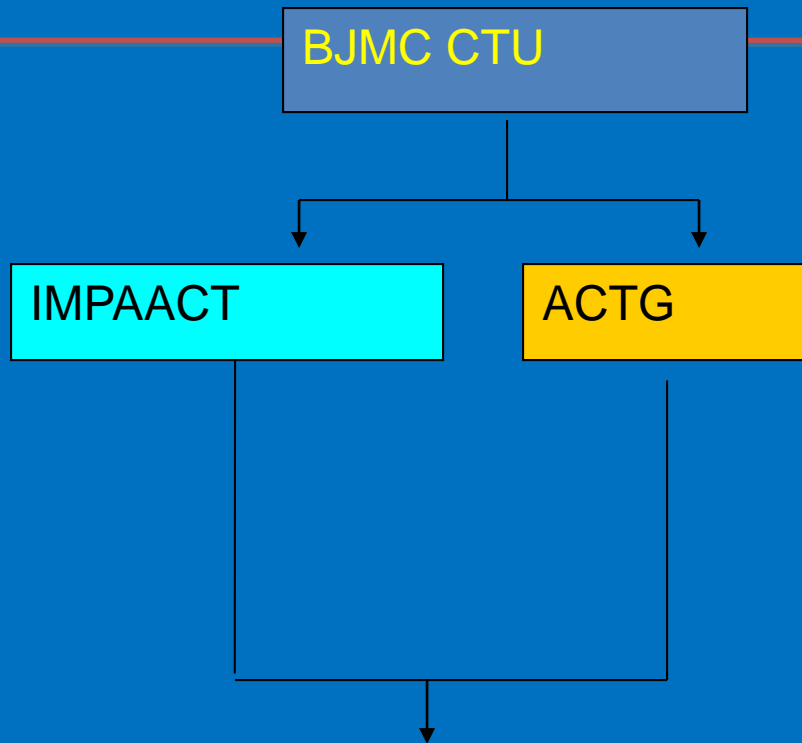
BJMC CRS Community Advisory Board (CAB)



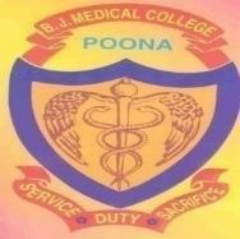
- Established in August 2000.
- Total No of Members: 15
- Diverse group composed of
 - Direct Stake Holders
 - Medical Doctors
 - Community Health Scientists
 - Advocates
 - Medical Social Workers
 - Journalists
 - Government Health Officials



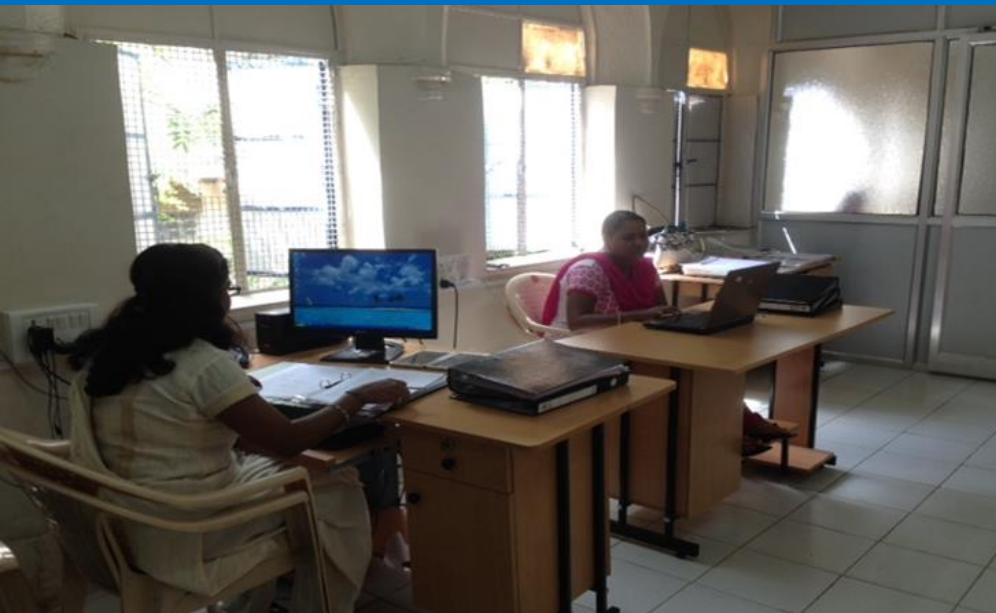
ACTIVITIES OF CAB



- All protocols are discussed in local language and approved after issues/questions raised by CAB were answered satisfactorily by researchers.
- Dissemination of protocols in the community and facilitating community trainings
- Translation of consent forms.
- Discussions of protocols with Co-investigators in India and US through Video Conferences.
- Patient education material discussed



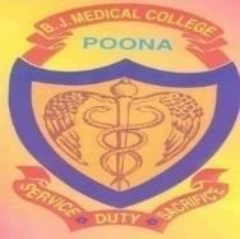
Data Management Center



Trained several data management members on quality control and data confidentiality

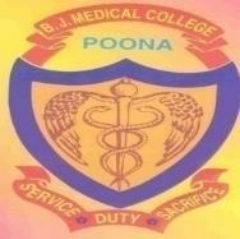
Moving to eCRFs and Medidata and RAVE for upcoming studies





BJGMC Research Pharmacy

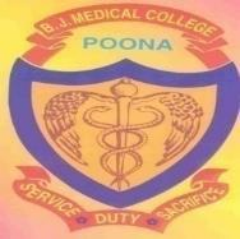




Pharmacy Facilities



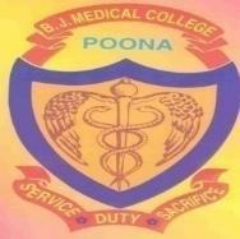
- Two big glass door refrigerators
- Two split air conditioners
- Open shelves fixed to the wall
- Metal cabinet for storage of the study products in central pharmacy.
- Two computers with internet and a printer/scanner/fax machine.
- Strong inverter battery back system in place in case of power failure and is also connected to a generator backup system



Research Counselling Units

- Maintain confidentiality
- Comfortable for participants

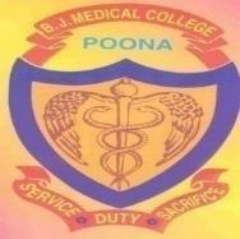




CRS Research Laboratory



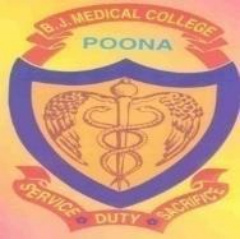
- CRS Research laboratory comprises facility of sample collection and processing, testing for safety labs, immunology, hemoglobin A1c for diabetes screening, cervical cytology, bacteriology, serology, molecular virology, PBMC processing and cryopreservation and large test menu.
- The CRS laboratory is DAIDS approved laboratory.



Specimen Repository



- The CRS lab maintains sample repository and stored thousands of various specimens like whole blood, Paxgene blood, whole blood for DNA, QGIT supernatant, plasma, serum, hair, nails, urine, saliva, sputum, biopsy specimens, cell pellets, viable PBMCs, breast milk, stool, cervical collections, perianal swabs, microbial cultures, MTB isolates etc.
- The repository has 10 -80C and 2 -20 freezers and 5 LN2 freezers. All freezers has generator and battery back ups with temp. monitoring system.



Quality Assurance

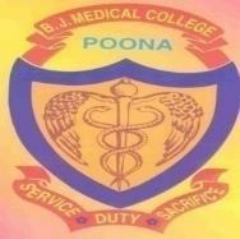


Internal QC:

- QC procedures are in place for all the tests using 2 and/or 3 level external controls that are performed in the lab.

External EQA

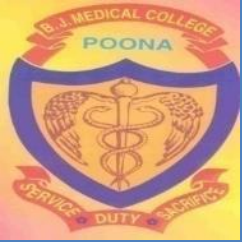
- College of American pathologists(CAP) 3x
- One World Accuracy(OWA) 3x
- UK NEQAS 6x
- IQA for PBMC and cryopreservation 4x
- VQA 4x
- NHLS South Africa for PAP cytology



TB Lab Capacity



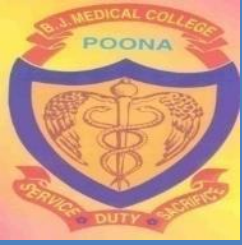
- We currently perform the following tests-
- 1) Microscopy : ZN & Fluorescent.
- 2) Gene Xpert
- 3) Liquid Culture by MGIT &
- 4) 1st line DST
- 5) Solid culture by LJ



Increased Capacity of TB Laboratory



- 1) Two Gene xperts :
 - a) IV /IV
 - b) b) XVI/VIII for accommodating the increased work load.
- 2) We are in the process of installing a new HAIN LPA for confirmation of multidrug resistant TB.
- 3) We are also validating the MGIT for second line drug sensitivity testing.



Quality Assurance



Internal QC:

- QC procedures are in place for all the tests that are performed in the lab.

External EQA

- We receive EQA from INSTAND for-
Microscopy/ Culture Identification/ DST-twice a year.

For Gene Xpert we receive EQA from Smart Spot Quality (Pty) Ltd- thrice a year.