RSSDI INDIAMET Study

INDIAMET(Indian Metabolic Profile) Study

- A Cross sectional nation-wide study of cardiometabolic profile of Indian adults
- **Short Title:** INDIAMET STUDY
- **Funder:** Research Society for Study of Diabetes in India
- **Protocol Date:**

INDIAMET(Indian Metabolic Profile) Study

- **Study Principal Investigator:** Dr Brij Mohan Makkar, Delhi
- Co-PIs – All RSSDI EC members
- Study co-ordinators – All the RSSDI members who volunteer to participate

INDIAMET(Indian Metabolic Profile) Study

1. Background Information and Rationale

1. Introduction and Need for the study

- Prevalence estimates of type 2 diabetes and cardiometabolic risk factors in the Indian population are limited. The only nationwide data we have are from ICMR-INDIAB study and National Family Health Surveys. The recently released "Metabolic non-communicable disease health report of India: the ICMR-INDIAB national cross-sectional study (ICMR-INDIAB-17) Ranjit Mohan Anjana et al." [1] has estimated the overall weighted prevalence of diabetes at 11·4% (95% CI 10·2–12·5; 101 million adults). The prevalence of diabetes and other metabolic NCDs in India is considerably higher than previously estimated
- ICMR-INDIA study is a well designed and well executed study which evaluated the prevalence of diabetes and its comorbid conditions in Indian population across all states, though it took more than a 15 years to complete the study.

INDIAMET(Indian Metabolic Profile) Study

1. Background Information and Rationale

1. Introduction and Need for the study

- To the best of our knowledge, there is no single study that has assessed the metabolic profile and cardiovascular risk factors of Indian people in a population based cross sectional nationwide study.
- This study aims to fill this gap.
- About RSSDI: The study will be conducted by RSSDI(Research Society for the Study of Diabetes in India). RSSDI is the largest society of diabetes physicians, endocrinologists and primary care physicians in India with a membership of more than 10700, has 23 state chapters and 900+ district coordinators and pan-India presence.

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STUDY OBJECTIVES

Primary Objectives

- To assess the metabolic profile of Indian Adults
- To assess the prevalence of cardiovascular risk factors in the population screened

Secondary Objectives

- To assess the prevalence of diabetes in the population screened
- To assess the prevalence of young onset diabetes in the population screened
- To assess the prevailing treatment practices and rural urban differences relating to diabetes and hypertension management

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- **Study design** - Prospective cross sectional observational real world study
- **PICO Summary**

- **Population :** All adults 18+ years
- **Intervention**: Measurement intervention only i.e. known lab tests and no treatment intervention
- **Comparator**: Descriptive study, comparison by geography and patient cohorts from the same sample
- **Outcome**: Prevalence of metabolic risk, metabolic disorders and treatment practices in the screened population

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- **Inclusion Criteria**

- Adults >=18 years
- Indian citizen
- Consent to participate
- **Exclusion Criteria**

- <18 years old
- Does not consent or is incapable of providing consent
- Hospitalized patients
- Any acute illness

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- **Geographic Coverage**
- All India excluding the following states / UT's
    - Jammu , Kashmir , Ladakh, Arunachal Pradesh, Manipur, Andaman and Nicobar islands, Lakshadweep
- India has 766 districts and these states / UT's combined are 68 districts, their contribution to population is only about 2%

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Sr No.	State
1	Andhra Pradesh (AP)
2	Assam (AS) + Sikkim
3	Bihar (BR)
4	Chandigarh (CH)
5	Chhattisgarh (CG)
6	Gujarat (GJ)
7	Haryana (HR)
8	Himachal Pradesh (HP) + Uttarakhand (UK)
9	Jharkhand (JH)
10	Karnataka (KA)
11	Kerala (KL)
12	Madhya Pradesh (MP)
13	Maharashtra (MH) + Goa
14	Meghalaya (ML) + Mizoram + Nagaland + Tripura
15	National Capital Territory of Delhi (DL)
16	Odisha (OD)
17	Punjab (PB)
18	Rajasthan (RJ)
19	Tamil Nadu (TN) + Puducherry
20	Telangana (TS)
21	Uttar Pradesh (UP)
22	West Bengal (WB)

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Sampling and Sampling Unit

- In this study we are taking the Household (HH) as the sampling unit. All eligible adults in the HH will be asked for consent and interviewed.
- The sampling proposed for this study is Voluntary and Purposive. Given the objectives of the study, fundings and time available we believe this is the best way forward. Our overall intent remains to achieve

a) Sample in all 22 units as in table 1

b) Have representation from Urban (all town classes) and Rural from each state

c) Have representation of all socio-economic groups

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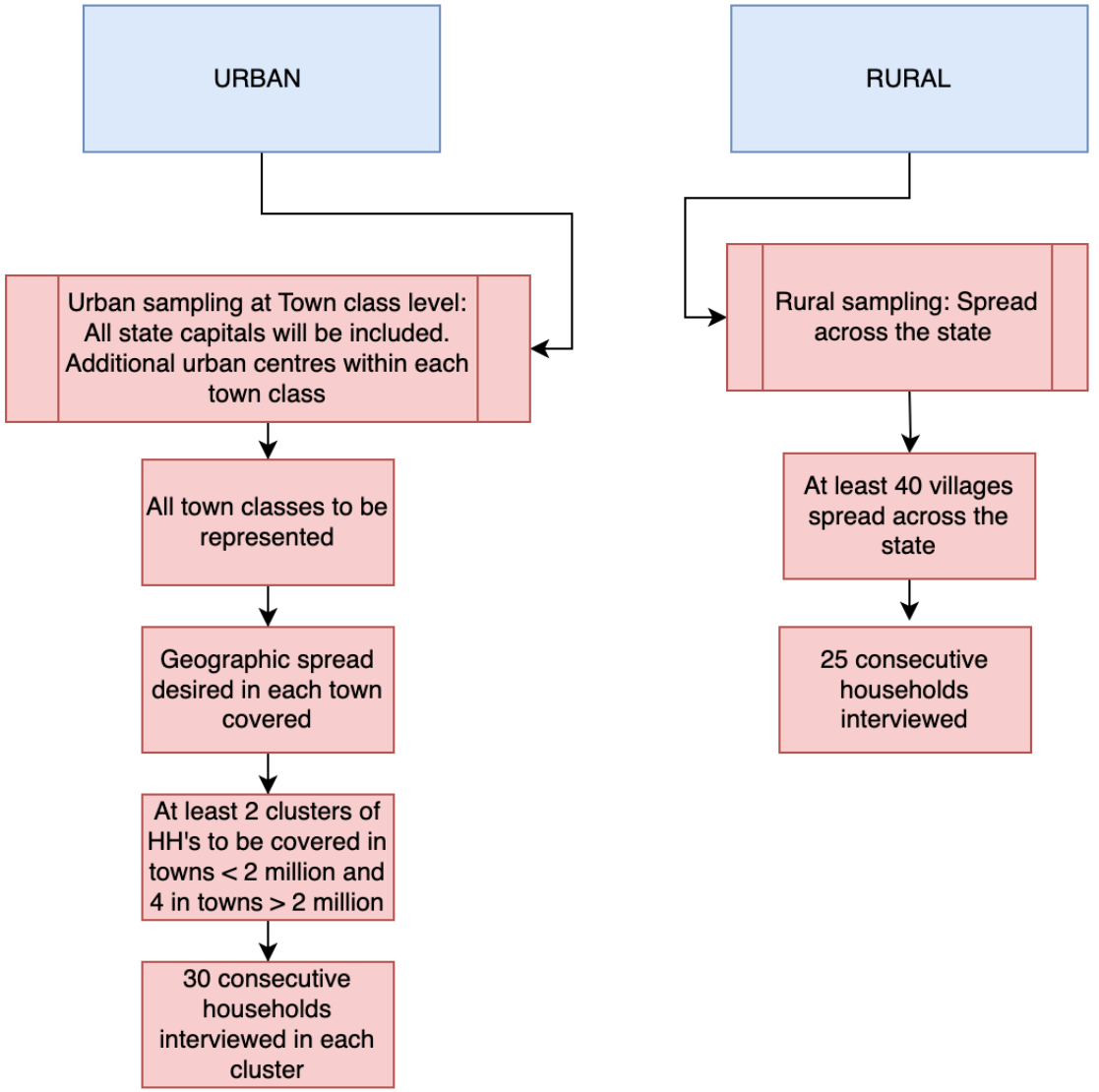
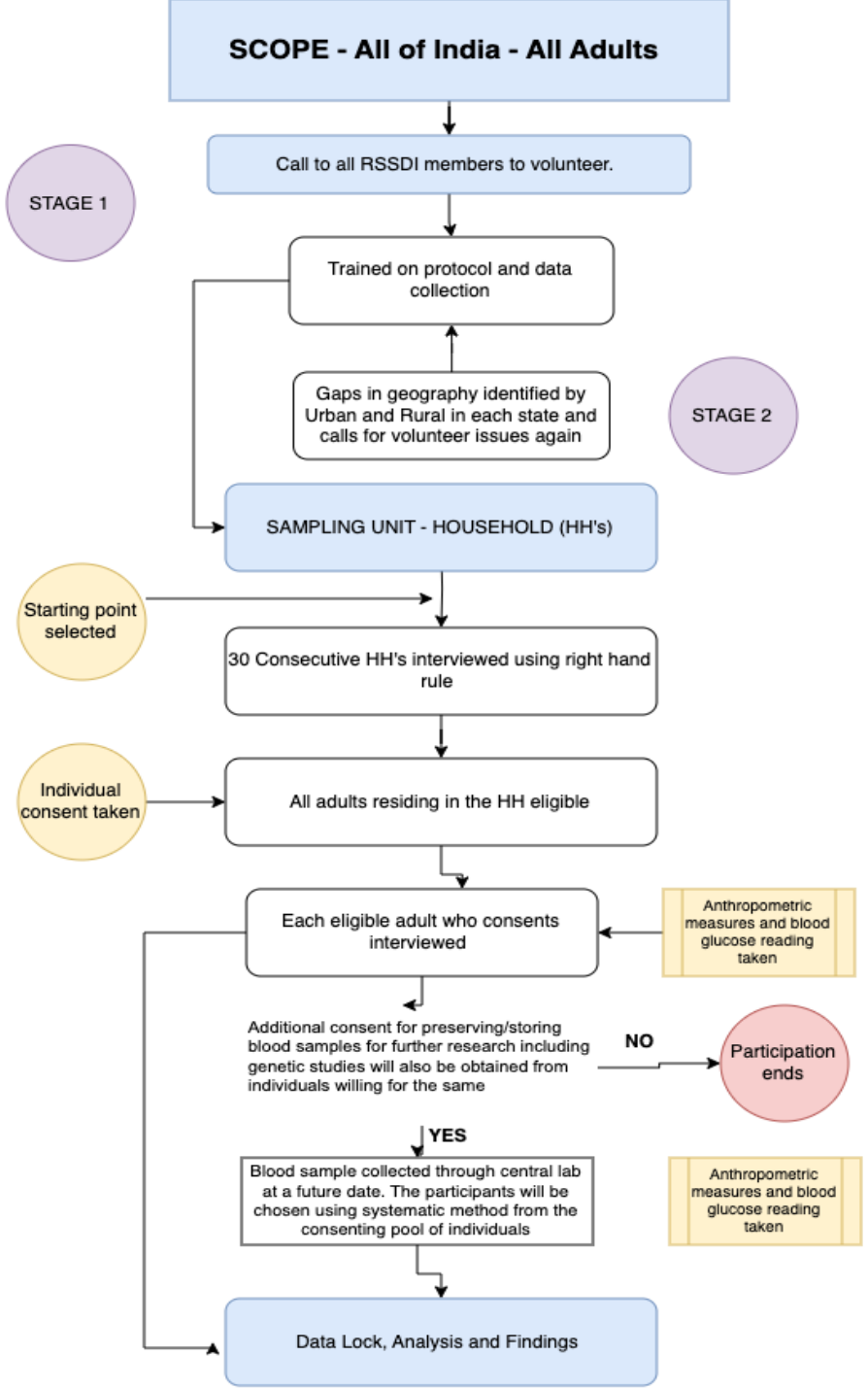
- The steps in sampling proposed are
  - STAGE 1 : Invite ALL (10000+ members) to participate
  - Map all volunteers location based on state, town class and GPS coordinates
  - STAGE 2 : The intent of RSSDI in Urban and Rural areas of each state needs to be met - see fig 1.0
    Gaps from stage 1 will be filled in by approaching relevant members with a request to participate.
    For village coverage, the nearest volunteer will be assigned.

INDIAMET(I Study




SCOPE - All of India - All Adults
Call to all RSSDI members to volunteer.
STAGE 1
Trained on protocol and data collection
Gaps in geography identified by Urban and Rural in each state and calls for volunteer issues again
STAGE 2
SAMPLING UNIT - HOUSEHOLD (HH's)
Starting point selected
30 Consecutive HH's interviewed using right hand rule
Individual consent taken
All adults residing in the HH eligible
Each eligible adult who consents interviewed
Anthropometric measures and blood glucose reading taken
Additional consent for preserving/storing blood samples for further research including genetic studies will also be obtained from individuals willing for the same
NO
Participation ends
YES
Blood sample collected through central lab at a future date. The participants will be chosen using systematic method from the consenting pool of individuals
Anthropometric measures and blood glucose reading taken
Data Lock, Analysis and Findings

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- SAMPLE SIZE
- Sample size was estimated to be
- 1600 in urban areas and
- 1000 in rural areas in each of the regions studied [Table 1],
- with a total of 2,600 per state and thus the total sample size of **57200** Adults

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- DURATION OF STUDY – 2 MONTHS

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- DATA COLLECTION
- SAMPLING BY COORDINATORS
- Based on the GPS coordinate of the practice the nearest residential cluster will be identified in the North / South / East / West direction. Each volunteer will be assigned a direction sequentially. If the practice is in a residential location then the starting point will be taken as the 30th HH from the practice location.
- The subject can opt out of the study at any time.

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SUBJECT IDENTIFIERS

- Name
- DOB
- Mobile no.
- Socioeconomic status
- Educational status
- Metro city/tier 2/3 city/ town/ village
- Area Pin Code

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Study Evaluations and Measurements

- **RESPONDENT HISTORY**
- DM
- CAD
- PTCA
- CABG
- STROKE
- HTN
- Fatty Liver (Previous USG)
- SMOKING
- ALCOHOL
- Family history – DM, CAD, HTN, ASVCD

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Study Evaluations and Measurements

- **ANTHROPOMETRIC MEASUREMENT**

- Height
- Weight
- Waist circumference
- Hip Circumference
- SBP/ DBP
- Blood Sugar – RANDOM

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STUDY EVALUATIONS AND MEASUREMENTS

- **ADDITIONAL DATA - INDIVIDUALS WITH KNOWN DIABETES**
  - CURRENT TREATMENT – No. of drug classes – 1/2/3/4/5
  - SU / METFORMIN/ IMEGLIMIN/ DPP4/ PIO/ SGLT2 / AGI / GLP1 RA/ INSULIN
  - Adherence to therapy
- **ADDITIONAL DATA - INDIVIDUALS WITH KNOWN HYPERTENSION**
  - CURRENT ANTI-HYPERTENSIVE TREATMENT: No. of drug classes – 1/2/3/4/5
  - ACE inhibitors / ARB/ Diuretics/ Calcium channel blockers/ Beta blockers/ Alpha blockers/ Centrally acting agents
  - Adherence to therapy

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Study Evaluations and Measurements

- **FOR THOSE WHO PROVIDE CONSENT FOR Complete Metabolic Profile (ABOUT 10% OF SAMPLE)**
- Urine Analysis/ACR/ CBC/ HbA1C/ Lipid Profile/ KFTs / LFTs/ TSH/ Vitamin D/ PTH/ S. Insulin/ C-peptide

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STUDY ROLL-OUT

MID-SEPTEMBER 2023