

What is the ICSSC?

International Clinical Sciences Support Center

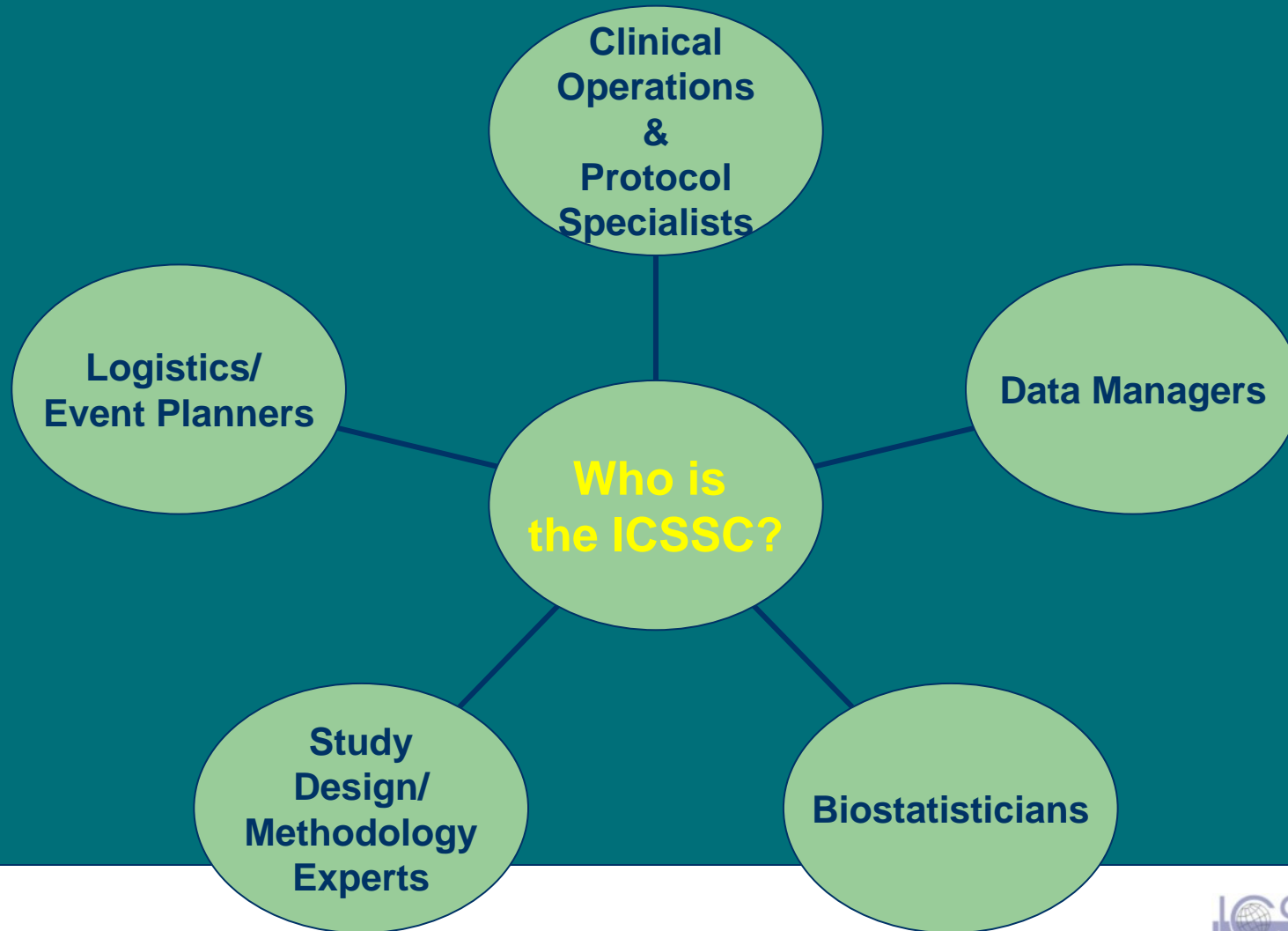
DMID/ICSSC

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What is the ICSSC?

- ✦ A Center established by DMID to assist investigators funded by NIH/NIAID/DMID conduct research at resource-constrained foreign sites
- ✦ Located at Family Health International (FHI), a diverse public health research organization working mainly in the developing world
- ✦ Composed of an interdisciplinary team of experts in various areas of clinical research

Who is the ICSSC?



What are the ICSSC Services?

◆ Protocol Review

- Clarity
- Completeness
- GCP compliance
- Proper use of DMID protocol templates

http://www.icssc.org/templates_resources.htm

What are the ICSSC Services?

✦ In-depth protocol assistance

- Study design consultation
- Statistical considerations
- Implementation planning
- Data management
- Safety monitoring and reporting
- Informed consent
- Good Clinical Practices (GCP)

What are the ICSSC Services?

✦ Site assessment

- Human resources
- Clinical facility
- Laboratories
- Pharmacy or drug preparation and storage facilities
- Information systems and communication
- Data management
- Ethics Committees
- Good Clinical Practices (GCP)

What are the ICSSC Services?

✦ Monitoring

- Confirm adequate qualifications and resources
- Verify investigational products
- Verify informed consent obtained
- Confirm performance of study functions
- Verify participant eligibility
- Confirm accuracy/ completeness of source docs & CRFs
- Verify all investigator-required reporting
- Determine timely reporting of adverse events
- Ensure maintenance of essential documents

What are the ICSSC Services?

- ◆ **DM assistance prior to study initiation**
 - Protocol data management section
 - Data management plan
 - Standard Operating Procedures (SOP)
 - Case Report Forms (CRFs)
 - Computer system validation plan

What are the ICSSC Services?

- ✦ **DM on-site assistance (after study initiation)**
 - Check compliance with DM plan
 - Check SOP compliance
 - Match batch tracking forms to database contents

What are the ICSSC Services?

✦ Biostatistics Services

- Study design consultation
- Endpoint definition
- Sample size determination
- Analysis plan development
- Randomization and allocation concealment procedures

What are the ICSSC Services?

✦ Biostatistics Services

- Case report forms review
- Interim reports for Data and Safety Monitoring Boards (DSMB)
- Final data analysis and interpretation of results
- Preparation of final report/manuscripts
- General biostatistical consultation and training

What are the ICSSC Services?

◆ Training

- Regional clinical research workshops
- Data management workshops
- Ethics training
- GCP training
- Scientific writing workshop
- Protocol-specific training
- Grant writing workshops
- Laboratory safety training
- Informed consent training
- Quality management training
- Others

Summary

- ✦ ICSSC can provide support during protocol development as well as during the study planning and implementation phases
- ✦ We provide a range of service including site assessments, monitoring, biostatistics support, data management support, training

Requesting Assistance

- ✦ Request for assistance can come from an investigator with a qualifying NIH grant or a DMID Program Officer
- ✦ Send request through:

<http://www.icssc.org/>