

## Ethical research is grounded in quality data: a clinical data management workshop in Varanasi

PARITOSH MALAVIYA<sup>1</sup>, RAFFAELLA RAVINETTO<sup>2</sup>, SHYAM SUNDAR<sup>3</sup>

<sup>1</sup> Head, Data Management Unit, Institute of Medical Sciences, Banaras Hindu University, Varanasi INDIA e-mail: paritosh\_malaviya@yahoo.com, <sup>2</sup> Head, Clinical Trials Unit, Institute of Tropical Medicine, Antwerp BELGIUM e-mail: rravinetto@itg.be, <sup>3</sup> Professor, Department of Medicine, Banaras Hindu University, Varanasi INDIA e-mail: drshyamsundar@hotmail.com

Research ethics is closely related to scientific and methodological standards. A research project involving human participants is never ethical if it is not scientifically and methodologically sound in the first place. Clinical data management, despite often being perceived as "just" a technical methodological service, plays in fact a key role in ensuring that data collected within a medical research are true, accurate and reliable; that subjects' privacy and confidentiality are duly ensured, and that the study findings will serve the interests of individual and public health.

In order to share and analyse the challenges faced by clinical data managers engaged in North-South and South-South collaborative medical research, a meeting was organised in Varanasi on March 4-8, 2013, by the Banaras Hindu University together with the Institute of Tropical Medicine in Antwerp (Belgium), in the framework of the Switching the Poles network,

Association for Data Management In the Tropics ( <http://admit.tghn.org/> ). The workshop was funded by the development agency, Belgian Technical Cooperation.

The meeting was attended by 18 participants from India, Nepal, Cambodia, Benin, Burkina Faso, the Gambia, Ghana, Kenya, Malawi, Rwanda, Belgium and the UK. The group spent five days together, sharing experiences from the different countries and settings, and trying to find together answers to the most frequent challenges they face. Such challenges are mainly due to the constraints in financial or human resources allocated to non-commercial research; the limited availability of appropriate tools and technologies, especially when working in remote research sites; and the lack of harmonisation, especially in multi-site research, or when pooling data from different research projects.

### Publisher's Note Form IV (See Rule 8)

- |    |                      |   |   |
|----|----------------------|---|---|
| 1. | Place of Publication | : | FORUM FOR MEDICAL ETHICS SOCIETY<br>0-18 Nav Bhavna Premises Co-op Society,<br>2nd floor, Veer Savarkar Marg, Prabhadevi, Mumbai 400025. Maharashtra. |
| 2. | Periodicity          | : | Quarterly.  |
| 3. | Printer's name       | : | Dr Sanjay Nagral  |
|    | Nationality          | : | Indian  |
|    | Address              | : | FORUM FOR MEDICAL ETHICS SOCIETY<br>0-18 Nav Bhavna Premises Co-op Society,<br>2nd floor, Veer Savarkar Marg, Prabhadevi, Mumbai 400025. Maharashtra. |
| 4. | Publisher's name     | : | Dr Sanjay Nagral  |
|    | Nationality          | : | Indian  |
|    | Address              | : | FORUM FOR MEDICAL ETHICS SOCIETY<br>0-18 Nav Bhavna Premises Co-op Society,<br>2nd floor, Veer Savarkar Marg, Prabhadevi, Mumbai 400025. Maharashtra. |
| 5. | Editor's name        | : | Dr Amar Jesani  |
|    | Nationality          | : | Indian  |
|    | Address              | : | FORUM FOR MEDICAL ETHICS SOCIETY<br>0-18 Nav Bhavna Premises Co-op Society,<br>2nd floor, Veer Savarkar Marg, Prabhadevi, Mumbai 400025. Maharashtra. |
| 6. | Name of Owner        | : | FORUM FOR MEDICAL ETHICS SOCIETY  |
|    | Address              | : | 0-18 Nav Bhavna Premises Co-op Society,<br>2nd floor, Veer Savarkar Marg, Prabhadevi, Mumbai 400025. Maharashtra.                                     |

I, Dr, Sanjay Nagral, hereby declare that the particulars given above are true to the best of my knowledge and belief.

Sd/-

31 March 2013.