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INTERNATIONAL EXPERTS RECOMMEND DEVELOPMENT OF A NEW “STANDARD” FOR BIOBANKS

The Marble Arch International Working Group on Biobanking for Biomedical Research, an international group of leaders of research biobanks, today announced its support for an international standard for accreditation of research biobanks.

At its recent meeting hosted by the Biobanque de Picardie in Amiens, France, the Marble Arch Group lent its support to the work being done by the French national normalisation authority (Association Française pour l'Assurance de la Qualité / Association Française de Normalisation - AFAQ / AFNOR Certification) and supported by the INSERM (Institut National pour la Santé et la Recherche Médicale), to create a national standard that may be applicable to other countries and form the basis of a new International Standards Organisation (ISO) standard.

This draft French standard, based on existing ISO standards and the guidelines for “Biological Resource Centres” published by the OECD, creates a set of standards that are specifically aimed at the quality management issues affecting research biobanks.

Celine Druetz-Verite of AFAQ/AFNOR predicted that the new “Norm” would be completed by the end of 2007 and would be piloted through certifications of a small number of biobanks in France to test the system. She said: “if appropriate, it might then also be possible to test the standards in an international setting outside of France as the first step to these becoming an international standard likely to be adopted by the International Standards Organisation.”

Dr Brian Clark, chief executive of onCore UK and a participant in the Marble Arch Group, said: “at present there is no obvious national or international

standard against which research biobanks can implement their quality management systems. Although many aspects of the ISO9001 standard are generically applicable, this standard does not go far enough to cover the specialist activities undertaken in biobanks.”

Dr Fay Betsou of the Biobanque de Picardie, said that “many research biobanks are familiar with the need for quality control of the samples they hold and provide to researchers. However, many have yet to embrace a quality management system to assure the quality of the samples and service that they provide”.

Currently international standards exist for laboratories conducting medical diagnostic work and for repositories holding and supplying reference samples and materials. However, the group of experts participating in the Marble Arch Group meeting observed that no existing standard met the needs of research biobanking.

Peter Geary, director of the Canadian Tumour Repository Network and a leading voice within the Marble Arch Group, said: “defining an international standard for quality management in research biobanks will be a significant step towards international harmonisation in the field and will help to ensure that biobanks achieve their common goal of supporting high quality biomedical research.”

“At present, it is difficult to answer some of the most pressing research questions using samples from a single bank, as the number of samples is often too small. This is especially the case where rare diseases are concerned. Different banks may also use different methods to prepare and preserve material, affecting consistency when scientists use samples from multiple sources. Harmonisation of approaches through the use of a commonly accepted quality management standard will help sort this out.”

The Marble Arch Working Group is also currently considering issues related to: medical information management and technology; the impact of privacy

laws in different countries on research; and economic analyses of research biobanks in different countries.

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Notes to editors:

*** About onCore UK**

A charitable cancer biobank founded through a collaborative funding partnership with the Department of Health (England), the Medical Research Council (MRC) and Cancer Research UK (CRUK). onCore UK's role is to serve as a national cancer biobank acting as an honest broker of donated samples: to source, process and protect samples donated by patients and ensure their high quality so that researchers can use them for research into the discovery and development of new means of preventing, diagnosing or treating cancer. onCore UK is an active participant in the Marble Arch International Working Group on Biobanking for Biomedical Research, was a co-founder of the Group and hosted its first meeting in London in December 2005. www.oncoreuk.org

*** About the Marble Arch Working Group**

Formed in London in December 2005, the Marble Arch International Working Group on Biobanking for Biomedical Research is an informal collective of opinion leaders in the field, who meet periodically as a "think tank" to discuss the practical issues affecting their work, to share knowledge and expertise and to foster advances in the field of research biobanking. Participants are derived from many countries around the world and participate on an invitation basis. Previous meetings have taken place in London (UK), Madrid (Spain) and San Paulo (Brazil). <http://www.marblearchgroup.org/>