Message From the President

I am privileged to be your President for the year ahead. Our Society is in a continued growth phase and that makes us an increasingly diverse, international biobanking community. Our annual meeting, held this year in Arlington, Virginia, was well attended. It was a fantastic opportunity to network with colleagues, and learn about ongoing and new biobanking initiatives that are having a major impact on public health and the environment. The breadth and activity of the ISBER membership was demonstrated by the large number of abstracts and platform presentations that spoke to the “Impact and Public Benefits of Biorepositories.” ISBER members and invited speakers gave impressive presentations on population, clinical, environmental and museum banks. There were lively exchanges of information during the working group discussions and a new session focused on Innovative Technologies that highlighted submitted presentations on the science and validation behind new products and technologies that have the potential to impact biorepository operations and specimen management/workflow. ISBER also welcomed the opportunity to invite our membership to the “UMN Conference: Should We Return Individual Research Results and Incidental Findings from Genomic Biobanks & Archives?” This meeting was a stimulating and fascinating set of sessions that included legal and ethical views from the global medical research community.

Many exciting ISBER activities are in progress this year! It has started with the introduction of the European, Middle-Eastern, and African Society for Biopreservation and Biobanking (ESBB) chapter of ISBER. Their inaugural meeting will be held in November 2011 in Marseille, France. (To find out more about ESBB, please visit: www.esbb.org) The growth of our Society also is a testament to the interest, significance, and impact of biorepositories around the world. Challenges to our environment, including the recent massive earthquakes experienced in Asia as well as the new health epidemics

(Continued on page 3)

Editor’s Corner

This year’s ISBER Annual Meeting was a huge success, with over 525 registrants, and all of our booths sold out (and we had vendors on the waiting list – how great is that for interest?) Wow, call us The Little Society That Could; we just keep growing and improving. It was great catching up with colleagues, seeing all the vendors’ booths, and learning from so many good presentations, abstracts, and workshops. (My only problem was that I needed to clone myself to take it all in.) Many thanks to the meeting organizing committee for organizing such a great program!

We welcome new president Marianne Henderson’s inaugural column in this issue, and look forward to many great advances for the society under her leadership.

(Continued on page 2)
I especially appreciate how ISBER has grown after going back through my records from our start-up years 1999-2001, and I can never thank our founding group enough for their hard work and persistence, especially Frank Simione and Phil Baird, who sponsored our first organizational meeting at ATCC, and Jim Vaught of NCI, who enabled ISBER to be officially started in a final session of an NCI-sponsored biorepository meeting in 2000. (Those records are now consolidated and stored with ASIP so that our early history will be safely preserved for the future.)

As always, I am intrigued by various articles from Andy Zaayenga’s weekly news summary for the membership. One article that really caught my attention was this one:

Q&A: Why small is beautiful - Large sample sizes are not the be-all and end-all of clinical research

The Scientist, June 15, 2011

“Early stage research often gets dinged for not including enough trial subjects to be statistically valid. But adhering to the large sample-size dogma is counterproductive, says Peter Bacchetti, a biostatistician at the University of California, San Francisco. Large sample sizes waste time on unsuccessful ideas as most early stage trials fail, and can even prevent innovative treatments from moving forward if trials that don’t recruit enough patients are never performed, he argues in a perspectives piece published online today in Science Translational Medicine” (http://the-scientist.com/2011/06/15/qa-why-small-is-beautiful/).

Definitely food for thought! And another one that everyone should read is “The Use of Human Tissues in...” (Continued on page 3)
Message from the President (continued from page 1)

remind us of the need to strive for excellence in support of global health and well-being. The highest quality biospecimen science and biobanking will continue to be key components in reaching this goal. ISBER strives to be the leading international forum for promoting consistent, high quality standards, ethical principles and innovation in biospecimen banking by uniting the global biobanking community in support of recent and future challenges.

The ISBER listserv continues to be an invaluable and well-used tool to query for answers to questions from our global membership. The Education and Training Committee is busy with several initiatives including the 3rd Edition of the ISBER Best Practices document and its companion Self-Assessment Tool. All of the ISBER Working Groups are active “think tanks” that welcome member involvement. A new working group focused on creating an International Repository Locator has just been established as a result of member initiative. We look forward to the progress of this new group. We hope you continue to take part in these activities and encourage you to join in if you are interested. Please remember that ISBER’s official journal Biopreservation and Biobanking is always seeking new and innovative manuscripts from our research community. (For example, see the latest issue of Biopreservation and Biobanking for profiles of 18 Biobanks in China, demonstrating biobank growth in Asia.) It is important that we continue to be an active learning/teaching forum. Save the date for the ISBER 2012 Annual Meeting & Exhibits, Westin Bayshore Hotel, Vancouver, British Columbia, Canada on May 15-18, 2012. The meeting theme is “Keeping Step in an Evolving Global Research Environment: Biobanking for Now and for the Future.”

ISBER is successful because it is supported by a dedicated community of volunteers who provide their time to move forward the work that is the core mission of the membership. We are also very thankful and appreciative of the companies that manufacture and or provide the products needed in our biobanking work. Vendors also volunteer by contributing to the Society with leadership, and provide valuable input and sponsorship. On behalf of the ISBER leadership and for all of those on Council, I want to thank you for the opportunity to serve this Society. The success of the Annual Meeting is due not only to the Program Committee putting together the interesting symposia, the Education and Training Committee including innovative workshops, and the Marketing Committee finding new ways to reach out to new members, but also because so many member volunteers in ISBER share this preparation with an encouraging atmosphere of excellence. I look forward to working with you all this year!

Marianne K. Henderson, MS
US National Cancer Institute
ISBER President
What’s your type?

NEW System for high throughput isolation of gDNA from blood (3-10ml)

Purifying genomic DNA from valuable, large volume whole blood samples (3-10ml) requires a reliable, efficient purification system. The NEW ReliaPrep™ Large Volume HT gDNA Isolation System from Promega offers unparalleled automated purification performance for large volume blood processing.

Walk-away Convenience:
No operator intervention during 96-sample run.

Conserve Reagents:
Automatically adjusts reagent usage based on sample size.

Increased Productivity:
96 samples purified in less than 8 hours.

Robust Purification:
gDNA from fresh, frozen or hemolyzed samples.

Learn more and request a demo at:
www.promega.com/purifyblood

Promega
Smart Moves

1. **Biomatrica** (an ISBER Gold Corporate Partner) announces the appointment of **Dr. James A. Robb** as a member of their Scientific Advisory Board. Dr. Robb is a well-respected pathologist and scientist with over 45 years experience in the fields of molecular pathology, virology, and genetics. He currently serves as a Governor of the College of American Pathologists, an organization consisting of over 18,000 board-certified pathologists, and for the past few years has been a SAIC-Frederick Consulting Pathologist in the Office of Biorepositories and Biospecimen Research (OBBR), National Cancer Institute, NIH. Dr Robb also served on the Secretary of Health and Human Services’ Committee for Genetics, Health and Society Task Force on Oversight of Genetic Tests. Dr. Robb received his M.D. (cum laude) from the University of Colorado in 1965, and completed his pathology residency and molecular biology training at Yale University, before becoming a Senior Surgeon at NIH. After NIH, he moved to the Department of Pathology, University of California San Diego (UCSD), becoming a tenured Professor of Pathology before taking the position of staff pathologist and Director of Molecular Pathology and Cytopathology at Scripps Clinic, La Jolla, CA. He helped develop, and then became Medical Director of, HCA East Florida.

[Editor’s note: As a follow-up smart move, Dr. Robb was rapidly recruited by Elaine to become an ISBER individual member, which he promptly did. Jim will be a great addition to ISBER!]

2. Member and Councilor **Andy Zaayenga** was profiled as a member by *Laboratory Automation & Screening* in their electronic laboratory neighborhood. See the profile and Andy’s hiking pictures at [http://www.eln.slas.org/story/1/14](http://www.eln.slas.org/story/1/14).

Note From the 2011 ISBER Travel Awardee

I want to express my gratitude to ISBER for the opportunity to attend the ISBER 2011 Annual Meeting. Our institution currently is working on improving the processes related with the quality of data management and ethical issues of biobank samples. In Colombia we have legal and ethical standards surrounding the management of clinical samples, however, there are no specifics rules in the management of biobank samples. In this sense, my attendance at this important event allowed me to receive updated and specific information about these aspects.

The use of software in the data management was a very important point for our institution because we are in the process of developing software according to our needs. The workshop “Evaluation and Design of Information Management Systems for Biorepositories,” and the session “Technology and Informatics for Repository Operations,” gave me a guide on technical aspects to consider in developing the software and showed the advantages and disadvantages between purchasing and building software. I had also the opportunity to learn about a variety of software offered by vendors.

At the level of ethical and legal aspects many relevant conferences were presented both in the workshop and in the meeting. Conferences related to the use of informed consent, such as the one provided by Dr. Scott Jewell, will allow us to make adjustments to the informed consent document that we use currently in CIDEIM. Another topic that caught my attention was the reporting of research results to the donors of samples. There were very interesting discussions on this topic, with different points of view from experts from different countries. The experience shared by the speakers on this and other ethical and legal issues is something that I will discuss with the human research participant protection group at CIDEIM.

During the workshop I had also the opportunity to learn about some technical aspects on the cryopreservation of samples. Proper handling of samples and quality control was also a major theme in the presentation of the posters.

The experience of attending the ISBER meeting resolved several specific questions I had in relation to the management of biobanks, but mostly, it generated new ideas and expectations about the wide scope of biobanks and the work that we can do at CIDEIM. In order to continue learning from this community of experts, I would like to join ISBER in the coming year. Finally, I would like to congratulate the organizers of the event, which was extremely well coordinated.

Olga Lucia Fernández
International Centre for Medical Research and Training (CIDEIM)
Cali-Colombia

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Make a Charitable Contribution Today!
**ISBER Global Expansion Fund**
[http://www.isber.org/donate/global.cfm](http://www.isber.org/donate/global.cfm)
**Winner of the ISBER 2011 Outstanding New Product Award: The Chart MVE Variō Series Freezer!**

At the May 2011 ISBER Annual Meeting, members of the Marketing Committee had the challenge of reviewing new products presented by our vendors. Eleven of our 56 exhibitors asked to be considered for the inaugural ISBER Outstanding New Product Award. A panel of 4 judges with diverse backgrounds in the field of biobanking were tasked with evaluating all of the applicants. Their enthusiastic choice was the innovative Chart MVE Variō Series freezer, which has been created as an energy-efficient alternative for ultra-low temperature to cryogenic storage.

Here’s where the innovation comes in: The performance value of the MVE Variō Series begins with the completely dry sample storage area, which will maintain a user-defined temperature anywhere between -50°C and -150°C. The temperature profile remains consistent and unaffected by lid openings. While the lid is open, the MVE Variō Series automatically compensates by shortening the cooling cycle interval so that the storage space temperature does not increase above the desired range. Processing time is also improved due to rapid temperature recovery time upon introduction of warm racks and samples. A full complement of monitors, sensors and alarms provide constant feedback, helping to ensure the safety of all samples in the freezer. (Another innovative feature is that if necessary, the Variō can be easily retrofitted to operate as a conventional VP-LN₂ freezer!)

Eco-friendly engineering efforts resulted in the ability to produce a freezer that operates with less than 1% of the power consumption of many current ultra-low temperature, upright mechanical freezers. There are no additional HVAC requirements, no ozone-depleting chlorofluorocarbon (CFC) or hydrofluorocarbon (HFC) refrigerants, and zero CO₂ emissions.

With LN₂ consumption at only 12 L/day at -80°C, and power consumption at only 8 W, overall operating costs remain at approximately 1/10 that of mechanical freezers. The long-term value of the MVE Variō Series is also apparent from the affordable and simple preventative maintenance. (For a more specific estimate on the potential return on your investment, utilize the MVE Variō™ Cost Calculator at [www.chart.com](http://www.chart.com).)

**ESBB Inaugural Conference in Marseille, 16th – 19th November**

This conference marks an exciting opportunity for ISBER to get involved in biobanking developments in Europe, the Middle East and Africa. The conference was officially endorsed by ISBER earlier this year and since then ESBB itself has been granted ISBER chapter status.

It should certainly be a conference to remember, with a large number of outstanding speakers and plenary sessions that are both diverse and topical. There will be a wide range of other activities including contributed paper sessions, poster sessions, exhibitor booths, corporate workshops and working group activities. In addition, the conference venue is excellent; the coastal location is quite spectacular.

The conference theme is: “Identifying the challenges and the opportunities for biorepositories today and in...

(Continued on page 7)

**ISBER CORPORATE PARTNERSHIPS**

**Enhance your corporate image!**

**Gain competitive advantages!**

ISBER connects the biomedical research, informatics, and repository science community with the biotech and pharmaceutical industries through mutually beneficial partnerships.

- ISBER organizational members are invited to participate as Corporate Partners.
- Corporate Partnerships are designed to provide our member organizations additional high-visibility opportunities to highlight their company, products and services at the Annual Meeting and on the ISBER website, providing unparalleled opportunities to connect with professionals in the specimen collection and storage industry in global markets.
- Corporate Partnerships are renewable each year and support the educational initiatives of the Society through unrestricted educational grants at three levels of support:
  - Platinum Partnership, $15,000/year
  - Gold Partnership, $8,000/year
  - Silver Partnership, $4,000/year

See [http://www.isber.org/cp/](http://www.isber.org/cp/) for details on benefits!
ESBB Inaugural Conference (continued from page 6)

the next five years” and the wide-ranging plenary sessions will include:

- Next steps in biobank networking and harmonisation
- Biobanking Issues in Africa & the Middle East
- Challenges and opportunities in the collection of biospecimens in clinical trials
- Challenges and opportunities for Museum Biobanks and Environmental Specimen Banks
- Biobanking economics: how to justify and maintain long-term funding
- Ethical, legal and social issues presented by the advent of personalised medicine
- Networking of Veterinary biobanks
- Integrating research biobanking with the provision of healthcare services
- Scientific and technological advances that are helping to measure and to maximise sample quality

Confirmed invited speakers include: Fay Betsou, Roger Bjugn, Marianna Bledsoe, Christian Bréchot (keynote), Ann Cambon-Thomsen, Christian Chabannon, Michael Christman, Georges Dagher, Enric Mateu de Antonio, Jeanne-Hélène di Donato, Peter Doran, Michał Fabisiak, Maura Ferrari, Fiorella Guadagni, Paul Hofman, Hartmut Juhl, Jan Koschorreck, Jan-Eric Litton, Jackie Mackenzie-Dodds, Uwe Oelmueller, Peter Riegman, Elena Salvaterra, Tobias Schulte-in-den-Baumen, Ole Seberg, Simone Sommer, Tomasz Stadejek, Jim Vaught, Ingrid Walter and Kurt Zatloukal.

The conference aims to identify the major challenges and opportunities in biobanking in order to guide future activities of the Chapter. ISBER members who are interested in biobanking issues relevant to Europe, the Middle East and Africa, are strongly encouraged to attend.

About Marseille weather in November: The average high is 14°C or 57°F and the average low is 6°C or 43°F. Throughout the year, the skies are very often clear and blue with brilliant sunshine, so bring sunglasses!

ESBB is the European, Middle Eastern and African Society for Biopreservation and Biobanking: www.esbb.org.

Robert Hewitt, MBBS, PhD
Hewitt Biobank Consultancy
ISBER Publications Committee Chair

ISBER 2012 ANNUAL MEETING

SAVE THE DATE!

ISBER 2012 Annual Meeting & Exhibits
Keeping Step in an Evolving Global Research Environment:
BioBanking for Now and for the Future
Westin Bayshore Hotel, Vancouver, British Columbia, Canada
May 15-18, 2012

For complete program information visit:
www.isber.org
Principles of Biobanking for Clinical, Biological and Environmental Biospecimens and Bioresources: The Story of a Transdisciplinary University Certificate

It was almost a coincidence when two ISBER members and environmental cryobiologists, Erica Benson and Keith Harding, met another ISBER member and clinical biobanker, Fay Betsou, two years ago during a conference in Edinburgh. After the conference, they went together to a small local restaurant where they were to discover, over succulent Yorkshire pudding and Scottish beer, that they shared exactly the same approach to biorepository quality and biospecimen validation issues. They were all astonished because they had never expected to discover so many commonalities between the environmental (algae) and the clinical (human) biobank quality and validation questions. During that dinner, the idea of a common, transdisciplinary course came up.

Two years later, the Governance Board of the University of Luxembourg approved the continuing education program entitled “Principles of Biobanking for Clinical, Biological and Environmental Biospecimens and Bioresources,” which took place for the first time last month in Luxembourg, in collaboration with the Integrated Biobank of Luxembourg (IBBL). Over the months, Erica, Keith, and Fay came together again in Scotland to fine-tune the different elements of the course and their interactions. The initial course brought together 13 students from Belgium, Germany, Sweden, Switzerland, Italy, Iceland, Malta and Egypt. They have all been successful in the final examination, and thus have become the first to hold a University Certificate on Transdisciplinary Biobanking.

The course took them on a 3-week-long journey through the biospecimen’s lifecycle, from the natural (human or non-human) environment to the scientist’s bench. Throughout the course, students not only learned all the technical, scientific, economic, and legal aspects of biobanks, but also discovered biobanking interdisciplinarity, and how some specific questions have been tackled by either the environmental or the clinical sector.

The teaching team included Fay Betsou (who passionately undertook the quality, statistical and biospecimen science issues), Erica Benson and Keith Harding (who energetically undertook the environmental and cryobiology issues), and specialists in all areas of biobanking: Dr. Laurent Antunes (pathology), Dominic Allen (cost analysis and recovery), Rudi Balling (systems biology), Karsten Hiller (metabolomics), Michel Laborde and Marcos Pestana (biobanking IT), Anne Laure Morin (ethical and regulatory issues), and Jean-François Hausman from the Garbriel Lippmann Institute of Luxemburg (who joyfully surprised the students with an original educational game concerning analytical variability).

Here is what Dr. Rania Labib, who had the highest testing results, said “...Thanks a lot for the handy comprehensive material, and thanks for all the knowledge I gained. Thanks to all of the teaching and organizing team. It was my pleasure attending such a great course.”

Clearly, this University-based training, which proved to fill an existing need, could not have happened without ISBER, which because it is the only transdisciplinary biobanking society, allowed the “coincidence” of the initial meeting in Edinburgh, and catalyzed all the rest.


Above, the 2011 class in front of the Integrated Biobank of Luxembourg where some practical training took place.

ISBER Self-Assessment Tool (SAT)

Created by the ISBER Education & Training Committee to assist repository operators in determining how well their repository follows the ISBER Best Practices for Repositories.

The assessment is confidential and aimed at helping specimen collection centers strengthen their practices through the identification of areas in need of improvement.

Now available to nonmembers!

http://www.isber.org/sat/
Psoriatic Tissue Bank Based in Scotland

Being a virtual tissue provider is a little bit like playing Cupid: it’s a great feeling when you make a match.

One of the best things about being a virtual tissue biobank is matching surplus tissue that would otherwise have been destroyed with researchers who can put it to good use. On the flip side, it is very frustrating when you cannot fulfill an order. Thankfully, it doesn’t happen very often and at Tissue Solutions we take great pride in the quality of the service we provide, and enjoy the challenge of working hard to source (i.e., obtain) products. High-quality human tissues have become the gold standard for biomedical research, and reliable access to such material is a critical resource for many companies. Our clients often tell us that an inability to obtain high-quality human samples means they are forced to design experiments around whatever tissues they can get, rather than pursuing the most promising leads in their research. Because of this problem, our network of suppliers has grown organically in response to our clients research needs, and we can now source a wide range of tissues based on an extensive range of demographics and disease criteria. However, there are still some tissues that are very difficult to source.

One tissue we were unable to source from our existing suppliers was skin biopsy samples from subjects with psoriasis. We keep a log of requests that we are unable to source, and we noticed an increasing demand for this type of material. Psoriatic samples are needed to support research into psoriasis and psoriatic arthritis. Psoriasis is one of the most prevalent of all autoimmune diseases with 125 million (2 to 3% of the total population) sufferers worldwide, and has no cure. These tissues also provide an excellent model for studying the effectiveness of medications that might be useful in other diseases that involve the immune system, such as diabetes, lupus, autoimmune caused lymphomas and rheumatoid arthritis. Despite demand, there is restricted access to psoriatic lesions from human donors, mainly due to the fact that psoriatic skin is not normally removed surgically as part of the medical treatment for the condition, so there is no surgical surplus. Therefore, in order to collect these samples, the only option is to ask patients to voluntarily donate skin biopsies, which are excised with their normal treatment.

When a tissue is unavailable from our existing suppliers, we often offer our client the option of a feasibility study or a prospective collection. To organize a prospective collection, we contact our sources and ask them to collect the tissue of interest when it becomes available. Typically, these collections are surgical excess or post-mortem samples, and predicting a timeline collecting such samples can be difficult. We decided to undertake a collection for the psoriasis samples, due to the mounting requests for samples. Tissue Solutions has undertaken many such prospective collections on behalf of our clients, but this is the first time we have organized our own in-house prospective collection. For us to operate in this manner, the project involved a significant up-front investment of resources.

Our first task was an initial consultation process in which we contacted our existing network of contacts to initiate collaborations. Although many individuals worked in the required clinical field, we had a very limited response. Due in part to the difficulties of the different priorities

(Continued on page 12)

New Advertising Option in the ISBER Newsletter for Vendors

Vendor ads appear in the newsletter issue PDFs attached to the ISBER website, as well as in any print copies produced for meetings. (Newsletter advertising will not be included in the newsletter content published in Biopreservation & Biobanking, ISBER’s Official Journal.)

The following rate structure for ads has been developed:

1. Available Ad Sizes:
   - Full Page - 7" x 10"
   - 1/2 Page Horizontal - 7" x 4.75"
   - 1/2 Page Vertical - 3.25" x 10"
   - ¼ Page = 3.25" x 5"

2. Design Specifications for Ads:
   - 4-Color; High resolution Adobe PDF (with embedded fonts)

3. Pricing by Size of Ad:

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Special Benefit for Corporate Partners:
- Platinum Partners may receive a free full page ad;
- Gold Partners may receive a free 1/2 page ad;
- Silver Partners receive a free 1/4 page ad.

Contact Laurie Menser, Director of Marketing and Development, ASIP/ISBER. Tel: 301-634-7908, Fax: 301-634-7990, Email: lmenser@asip.org.
**Inter-Biobank Visits Scheme—The Victorian Cancer Biobank**

The Victorian Cancer Biobank (VCB), located in Melbourne, Australia, is a not-for-profit consortium of tissue banks, supported by the Cancer Council Victoria and the Victorian Government. When the consortium was formed in 2006, the four member tissue banks agreed to give custodianship of the samples to the Consortium. In our first four years of operating, more than 14,000 patients have donated blood and tissue samples.

The centralised Access Committee reviews applications to ensure biospecimens and data are only supplied for ethically approved research. In addition to supplying archival material from storage, the VCB also provides fresh tissue samples locally for preparation of cell lines and supports clinical research programs. Over the last four years, all 105 applications have been approved and more than 18,000 biospecimens were supplied to academic and commercial sector researchers worldwide.

The operational model is based on a ‘hub and spokes’ collection system. Biospecimens are collected from 27 private and public hospitals that form the spokes around the four Consortium member hub sites where tissues and blood samples are processed and biospecimen products are stored. In addition to the four major processing sites, tissues and blood are processed at three smaller sites and then transported for long term storage to the nearest hub site.

**Quality**

Our Quality Management System has been developed in line with ISBER best practices for repositories and the requirements of ISO 9001 and ISO 17025. Resident pathologists histologically examine each tissue specimen and subsequent H&E staining provides additional verification. However, with biospecimens being supplied from multiple sites, monitoring to ensure uniform high quality samples is even more important.

Staff are trained using the same SOPs at all sites and regular auditing and quality checks ensure compliance. During our last internal audit to the ISBER standard, a need was identified to make sure that all staff interpret the SOPs in the same manner. In order to achieve this, we introduced a voluntary Inter-Biobank Visits Scheme.

**Inter-Biobank Visits Scheme**

The Inter-Biobank Visits Scheme is designed to encourage discussion and address differences in processes between the Consortium member tissue banks. Staff at one site nominate areas of interest in the biobanking process that they want to improve and are then allocated a day at one of our other collection sites.

“Getting a tour of the histology lab at Cabrini and learning about how the lab runs, provided me with some ideas to then pass on to our Histology lab.”

_Katie-Lee Alexander,_

_Medical Scientist at Barwon Health_

This scheme is open to all members of the Consortium, from data managers to scientists and facility managers. Some of the areas of interest included blood and tissue processing, interpretation of pathology results, data entry, specimen storage, and management procedures.

One key component is the mandatory completion of a visit feedback form that is returned to the Quality and Training Manager, detailing benefits and differences experienced during the visit. Advantages have included the identification of parts of the SOPs that need to be updated.

(Continued on page 13)
**Biobanking Software Product: Labmatrix**

BioFortis, Inc. is a Maryland-based software company that is focused on addressing informatics challenges in today’s data-intensive environments. Its biobanking and scientific data management product, Labmatrix, is a web-based application that provides comprehensive donor and biospecimen management capabilities for pre-clinical, clinical, and other biospecimen collections for individual labs or across multiple collaborative sites.

Labmatrix supports biobanking data management in samples’ acquisition and usage lifecycle, as well as the associated clinical and research data resulting from different operational workflows. Using this software application, investigators can tightly link and track all data from donor clinical profile, consents, processing, storage, derivatives, and usage along with test results.

Labmatrix is utilized by numerous organizations to satisfy evolving scientific requirements and data exchange standards while maintaining compliance with institutional or government regulations for tracking human and non-human specimens.

**How is it different from other biobanking software?**

Labmatrix differs from other biobanking software by its emphasis on treating biobanking as an integral component of clinical and translational research, instead of a stand-alone operation. Labmatrix can function as an organization’s primary biobanking solution, or act as a unified interface for querying other existing databases to enrich biospecimen annotations with “upstream” clinical and “downstream” experimental data.

Data access is enabled by a graphical query tool that allows non-technical users to retrieve data about and around biospecimens of interest, while safeguarding patient PHI (Protected Health Information) - if necessary; these queries can span across all available patient-derived and specimen-derived information.

Labmatrix is scalable and flexible in implementation. Organizations can start from supporting a single lab’s sample management needs, and all the way up to large-scale, distributed, collaborative biobanking initiatives across multiple organizations. This enterprise-level system has a mature JAVA API and multiple connectivity interfaces that cater to institutional IT’s development and systems integration objectives.

**Case Study**

Since 2006, a large government research institute has been utilizing Labmatrix as its biospecimen information management platform. Scientists from multiple investigative divisions utilize Labmatrix to process and track information and events about biospecimens – such...

(Continued on page 13)

JOIN AN ISBER WORKING GROUP:

Identify and tackle important, unresolved issues related to specimen banking. ISBER members use their expertise and experience in subject areas below, and are committed to producing outcomes to biobanking.

- Automated Repositories
- Biorepository Funding and Promotion
- Biospecimen Science
- Clinical Biobanking
- Environmental Biospecimen
- Informatics
- Informed Consent Procedures for the Collection of Biospecimens
- International Repository Locator
- Pharma-Academia
- Rights to and Control of Human Tissue Samples

http://www.isber.org/wg/
within these groups, clinicians typically have a heavy workload and can only participate in such studies if it does not affect their day-to-day procedures. The feedback we received was that the resources required to set up the processes and procedures, coupled with a lengthy in-house administrative process, was too labor-intensive. Furthermore, many clinical sites had developed internal biobanks for their own researchers with internal policies governing access to their samples. This particular project was further complicated by the fact that the skin biopsies would have to be excised with normal treatment at no therapeutic advantage to the patient and paid for by the client. After several rounds of failed attempts to find a collaborator, the success of this particular project began to look unlikely. Our experience is that this stage of the project is always the most difficult and takes the most amount of manpower and patience.

The project ground to a halt, and just when it looked as if we would not be able to proceed, a chance encounter changed our luck. Morag McFarlane, our Chief Scientific Operating Officer had agreed to give a presentation to a local business group. A member of the group attending was a landlord, and he suggested that we contact one of his tenants, who turned out to be a CRO and was able to help with the collection.

Once a collaborating partner had been found, the project gathered momentum. We drafted and submitted a project application to the ethics committee on the basis of setting up a virtual biobank that would allow us to collect psoriatic tissue for researchers on demand for pre-clinical research projects, and ship the tissues directly to the researchers after collection. Our collaborators used the existing systems in place at their institutes for recruitment, informed consent, and data collection. As the samples were to be collected specifically for the project and not as surgical excess, as an extra precaution we opted to take an indemnity insurance policy. While the UK National Health Service insurance would cover damages caused by a physician’s negligence, we felt it was necessary to have additional insurance if anything went wrong for any other reason, as these biopsies are not scheduled procedures. The recruitment site agreed to provide samples of 3- to 5-mm skin biopsies from psoriatic patients at both lesional and matched non-lesional sites and 20-mL of blood, collected in tubes as specified by the client where required. To ensure high-quality fresh biopsies, we ordered AQIX® RS-I, Aquix Ltd, UK. Using this medium gave us the potential to ship fresh tissue that would retain cell potency worldwide. For frozen tissue, liquid nitrogen was used for flash-freezing, and the tissues shipped directly on dry ice.

With the project framework in place, we needed to organise paperwork and contractual agreements to protect our responsibility to the donors. We wrote agreements that covered access to the samples to ensure that samples would only be used in high-quality research relevant to the disease area. As part of this process, we set up a governance committee (completely independent of Tissue Solutions and established specifically for the psoriasis project) to vet the qualifications of researchers applying for tissues and the scientific veracity of their project applications. Committee members were selected from a wide background, and currently include scientists, a psoriasis sufferer, and lay people to give a balance of expertise and input. The committee was fully entrusted with access responsibilities, and given a mandate to evaluate enquiries within a few days of receipt and provide an answer within a week of the request. Although the group was given the authority over access to the collection tissues, the decision-making guidelines were laid out in the project plan so that all applications would be processed with the same criteria to ensure that the process would be fair and informed. Using an independent committee elected in this way ensured the neutrality of the decision-making process and provided confidence in the robustness of our ethics. We also set up a Material Transfer Agreement for the client to sign prior to release of samples to cover storage and disposal of the samples.

In January 2011, we were delighted to hear that our ethics application had been successful. This collection has allowed us to provide unique access for our clients to tissues which might be otherwise unavailable, and to facilitate research into psoriasis and related inflammatory conditions. This project required an extensive amount of planning and collaboration, and the central challenge has been in striking a balance between ensuring samples are affordable while maintaining the overall sustainability of the project.

At Tissue Solutions, we measure the success and relevance of any collection project by the demand for samples and the satisfaction of our clients. In all these respects, our first in-house prospective collection has been wholly successful, and we plan to undertake similar collections in new therapeutic areas in the future.

The psoriatic biopsies add an additional product to our list of human biomaterials that we can offer to our clients in addition to fresh, frozen, and formalin-preserved, paraffin-embedded tissues from a variety of diseases and other human biomaterials such as blood products, urine, CSF and brain material, fresh and frozen dorsal root ganglia. (For more information, check our website: www.tissue-solutions.com.)

Dr. Fiona Mackenzie
Senior Executive Scientist
Tissue Solutions
Victorian Cancer Biobank (continued from page 10)

or improved as well as the earmarking of areas where additional training is required.

“Since visiting Barwon Health, Cabrini Health Tissue Bank has implemented a similar paperwork workflow, and has revised their paperwork storage system, as well as implementing an emergency standard operating procedure for our -80 Freezer, as observed at Barwon Health.”
Lisa McPhail,
Tissue Bank Medical Scientist at Cabrini Health

Most of the sites are located across metropolitan Melbourne, which spans a 50-kilometre distance, with one site in a large regional centre located 100 kilometres away. This means that staff will usually interact by phone or email, only occasionally meeting at centralised workshops. The visits provide the new experience of working together and sharing skills and experiences.

“Being a city-based tissue bank, Melbourne Health has the benefits of being in close proximity to the sites they cover and having been established for ten years, their system is well ingrained. At Southern Health, covering four sites, over a distance of 30kms, we have adapted our own way of functioning that still enables prompt and viable collections.”
Elizabeth Blake,
Database Manager at Southern Health

Positive feedback has been received from all those who have participated in the scheme. They expressed a greater sense of ownership of their role and felt valued as members of a larger the group.

“The inter-Biobank visits are a very worthwhile experience, and help build great professional relationships between sites.”
Katie-Lee Alexander, Medical Scientist at Barwon Health
Matthew Chapman, Tissue Bank Manager at Melbourne Health

BioFortis—Labmatrix (continued from page 11)

as clinical and research data management of the originating human patient, barcode label generation, experimental data association, and historical logging of biospecimen custody transfers.

At the start of the biobanking process, a set of patient demographics data is synchronized from the institute’s electronic medical records system; subsequently, additional information about the patient sample donors are captured from a multitude of research activities and protocol-centric clinical observations based on the investigational division and nature of its studies - such as questionnaires, disease scoring, and clinical events.

Prior to patient procedures, scientific investigators attach pre-generated barcode labels to biospecimen containers and deliver them to phlebotomists and/or the surgical staff. With the acquisition of the biospecimens, this clinical event is associated along with other downstream processing information such as pathology results, custody transfer, storage inventory, sample aliquots, derivatives, slide images/annotations, and experimental or molecular assay data from the samples.

Individual patient reports can then be generated from real-time clinical, molecular, and study protocol data residing in Labmatrix, and distributed to research physicians in weekly grand rounds as reference information for the physicians to determine the next course of diagnosis or disease treatment.

The institute’s IT personnel manage user access, standardize resources and terminologies, integrate data streams, and develop study-specific projects on the Labmatrix framework to facilitate security compliance, code/data reuse, and maintenance.

For more information, go to www.BioFortis.com.

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ISBER 2011 Annual Meeting Photo Contest
Thank you to everyone who participated in the Inaugural ISBER Annual Meeting Photo Contest.

1st Place Photo
Submitted by Mary Cappellino

Honorable Mention
Submitted by Daniel Simeon-Dubach
Photo Credit: Dominic Allen - 3; Fay Betsou - 12, 13, 14; Bas de Jong - 6, 9; Marcel Kap - 11; Daniel Simeon-Dubach - 1, 2, 4; Simone Sommer - 5, 7