Disease Outbreak Detection in the Genomics Era: A Roadmap Forward

March 1st and 2nd 2012

US Food & Drug Administration / Danish Technical University

Agenda

Purpose

(i) To provide an expanded follow-up to the 2011 Brussels meeting and debate the short and long term obstacles and solutions for a global system for identification of microorganisms based on genomic information. (ii) To provide an overview of ongoing initiatives and discuss how global collaboration can be achieved. (iii) To determine a path forward for how to establish a globally distributed system.

Discussions

Will focus on solutions to questions and challenges surrounding the deployment of next-generation genomic typing tools for public health and clinical disease cluster detection on a global scale. Specific questions to be answered from this collection of worldwide experts in the field may include: (i) appropriate metadata attached to genome data submissions; (ii) available computer resources/tools required to implement and execute a global genome-based disease detection network; (iii) data types and categories to be included for databasing and analysis; (iv) political and legal impediments for the sharing of genomic data; and (v) data formatting for point-of-care clinical utility and public health.

Expected Outcome

A series of draft road map statements focused on establishing a global disease outbreak detection system using a worldwide network of shared genomic information for bacterial, viral, and parasitic microorganisms AND a commitment from various institutions for working together on developing such a database.

Day 1 - Agenda (March 1st, 2012)

Overview, Updates, Initiatives

8:30 AM	Welcome/Overview	E. Brown (FDA) / J. Schlunt (DTU)
9:00 AM	The Public Health Vision for Genomics	S. Musser (FDA)
9:20 AM	The Brussels Meeting 2011 Consensus Report	F. Aarestrup (DTU)
9:40 AM	Initiating a Global NGS Data Network: "The Digital Immune System"	D. Lipman (NCBI)
10:00 AM	The Current Revolution and future promise of Pathogen Sequencing	D. Rasko (IGS-UM)
10:20 AM	BREAK	

Molecular Epidemiology: Proofs of Concept

10:40 AM	Whole Genome Sequencing as a Molecular Epidemiologic Tool	J. Musser (Methodist)
11:00 AM	Whole Genome Sequencing of Foodborne Outbreaks	M. Allard/E. Strain (FDA)
11:15 AM	Comparative genomics of Vibrio cholerae from Haiti	G. Van Domselaar (PHC)
11:30 AM	Microarray-based re-sequencing breakthroughs	S. Jackson (FDA)
11:45 AM	QUESTIONS	
11:55 AM	LUNCH BREAK	

An IT Path Forward: Data Pipelines and Public Data Networking

1:00 PM	A Proposed Bacterial Pathogen Rapid Characterization Pipeline at NCBI	J. Ostell (NIH)
1:20 PM	NCBI Microbial Genome Resources: foundation for comparative genome analysis	T. Tatusova (NCBI)
1:35 PM	Sequence data services at EMBL-EBI	Guy Cochrane (EMBL)
1:50 PM	Pathogen Characterization Via k-mer Based Analyses	K. McLoughlin (LLNL)
2:10 PM	BREAK	

An IT Path Forward: Data Pipelines and Public Data Networking (cont.)

2:30 PM	Patho-Ngen-Trace: Next Generation Seqeuncing for pathogen diagnostics and epidemiology — S. Niemann (Borstel)
2:45 PM	KEGG MEDICUS and LinkDB — M. Kanehisa (KEGG)
3:00 PM	QUESTIONS
3:10 PM	Break-Out Session Charges — E. Brown
3:15 PM	Break-Out Session (Questions 1-3) — SIDE ROOMS
4:45 PM	Plenary Session — MAIN HALL
5:30 PM	*Adjourn DAY 1*

Day 2 - Agenda (March 2nd, 2012)

Bioinformatic Toolboxes

8:25 AM	Welcome to Day 2 — E. Brown/J. Schlunt
8:30 AM	Web based pipeline for Genomic Epidemiology — O. Lund (DTU)
8:45 AM	MicrobeNet: The Place to be for Bacterial Identification — J. McQuiston (CDC)
9:00 AM	Bioinformatics: Tools & Applications in Governmental Science — R. Stones (FERA)
9:15 AM	A Platform for Surveillance, Risk Assessment and Analysis: PATRN — R. Jain (PATRN)
9:30 AM	QUESTIONS

Clinical Perspectives on NGS-based Pathogen Identification System

9:40 AM	Pathogen Genomics in a Clinical Laboratory Setting — L. Bry (Harvard)
10:10 AM	Tracking Gram-negative nosocomial outbreaks at the NIH Clinical Center — J. Segre (NISC)
10:30 AM	Need for WGS and machine learning technologies in the clinical microbiology lab — G. Gerber (Harvard)
10:50 AM	Clinical Discussion Panel
11:00 AM	Break-Out Session #2 (Questions 4-6) — SIDE ROOMS
12:00 AM	Plenary Session — MAIN HALL
12:30 PM	LUNCH on your own

Health Policy Needs

1:30 PM	Barriers to Implementation of WGS — J. Schlunt (DFI)
1:45 PM	Interrelating microbial genomes with the world's microbial phenotypes — J. Stelling (Harvard)
2:00 PM	Information for action: examples and challenges in application of viral sequence data in an international public health arena — M. Koopmans (RIVM)
2:15 PM	Surveillance in a time without cultures — P. Gerner-Smidt (CDC)
2:30 PM	U.S. Regulatory Perspective: Performance Requirements for Diagnostics — U. Scherf (FDA)
2:45 PM	BREAK
3:00 PM	Break-Out Session #3 (Questions 7-10) — SIDE ROOMS
4:45 PM	Plenary Session — MAIN HALL
5:30 PM	SUMMARY OF ROADMAP MARKERS AND DELIVERABLES, CONTACTS FOR POLITICAL AND ECONOMIC BARRIERS, DATA MANAGEMENT PARTNERSHIPS, OBJECTIVES FOR NEXT MEETING - JOINING GOV'T HEALTH LABORATORIES AND ACADEMIA TO INDUSTRY AND POLICY
6:00 PM	*Meeting Adjourned*

Dr. Eric Brown is with FDA's Center for Food Safety and Applied Nutrition where he currently serves as a research microbiologist and the Director of the Division of Microbiology, Office of Regulatory Science. Dr. Brown received his M.S. in Microbiology from the National Cancer Institute at Fort Detrick, MD in 1993 and his Ph.D. in Microbial genetics from The George Washington University in 1997. After serving as an assistant professor of microbiology at Loyola University of Chicago from 1998 to 2000, he joined the laboratories at the Food and Drug Administration in January of 2000 and has since been engaged in a multi-parameter research program to develop and apply molecular genetic strategies for identifying and differentiating bacterial foodborne pathogens. By combining the latest tools of bioinformatics and molecular biology, Dr. Brown has reported on the genetic, phylogenetic, and molecular epidemiological relationships among numerous pathogenic strains. He is also focused on understanding the role of horizontal gene transfer in the emergence of new and dangerous pathogen phenotypes as well as the genetic etiologies of several currently emerging pathogens.

Dr. Jergen Schlundt is Acting Director at the National Food Institute, Technical University of Denmark. Dr. Schlundt has a veterinary degree as well as a Ph.D. from the Veterinary University in Copenhagen, Denmark. He worked at national level on environmental and food safety issues from 1983 to 1999, during which period he headed the Bacteriology Department at the Veterinary Research Laboratory in Harare, Zimbabwe for three years. From 1999-2010 Dr. Schlundt was Director of the Department of Food Safety and Zoonoses at WHO, Geneva. During the years, he participated in a number of international bodies, including OECD expert groups, WHO and FAO Expert Consultations, EU Scientific Committees, and the FAO/WHO Codex alimentarius Commission. Dr. Schlundt has participated in the international development of Risk analysis principles, including the use of scientific risk assessment as the basis for food safety management decisions. As part of this, he has overseen major new international initiatives, including the creation of the Joint WHO/FAO Joint Expert meeting on Microbiological Risk Assessment (JEMRA) and the International Food Safety Authorities Network (INFOSAN), the build-up of the Global Foodborne Infections Network (GFN), the initiation of the first-ever estimation of the global burden of foodborne diseases, and the development of a major consumer education programme on the Five Keys to Safer Food.

Dr. Steven Musser is currently the Acting Deputy Director for Regulatory Affairs at the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN). He has overseen an extensive research portfolio supporting a number of priority food and cosmetic programs, including counter-terrorism, dietary supplements, foodborne pathogens, food contaminants and natural toxins. He has directed the Center's research in precedent setting areas of food research, which include food allergen detection, methods for detecting chemical contaminants, dietary supplement analysis, and the use of proteomics for microbial epidemiology and classification. He has published numerous articles in the peer reviewed scientific literature and regularly speaks on research topics at national and international scientific meetings. Dr. Musser is a member of both the American Chemical Society and the American Society for Microbiology, along with several other professional societies. Dr. Musser received his B.S. degree in Biology from Millersville University and his Ph.D. in Medicinal Chemistry from the University of Maryland-Baltimore in 1989. He then completed a post-doctoral research fellowship at the National Institutes of Health, National Cancer Institute. He started his career at FDA in 1991 as a research chemist and became the Branch Chief of the Instrumentation and Biophysics Branch six years later. Prior to his current appointment, Dr. Musser was the Director of the Office of Regulatory Science at CFSAN. He still serves as the Center's Lead Scientist for Chemistry.

Dr. Frank Aarestrup is Professor in Microbiology at the National Food Institute, Technical University of Denmark and Head of WHO and EU reference laboratories for Antimicrobial Resistance. Dr Aarestrup has more than 15 years experience with national and global surveillance of antimicrobial resistance and infections diseases. Main research focus is to combine epidemiology with molecular microbiology and bioinformatics.

Dr. David Lipman is the Director of the National Center for Biotechnology Information (NCBI), a division of the National Library of Medicine within the National Institutes of Health (NIH). He was appointed as NCBI's first Director in 1989, shortly after Congress created the Center in 1988, and has overseen its growth into one of the most heavily used resources in the world for the search and retrieval of biomedical information, with about two million users each day. Dr. Lipman obtained a B.A. in Biology from Brown University in 1976 and an M.D. from the State University of New York at Buffalo in 1980. After medical training, Dr. Lipman joined the Mathematical Research Branch of the National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK) at NIH as a Research Fellow, studying molecular evolution and developing computational tools for sequence comparison. Dr. Lipman is one of the developers of the original BLAST (Basic Local Alignment Search Tool) algorithm for rapidly identifying biological sequences that are similar to a queried sequence. Dr. Lipman is the recipient of numerous awards and is an elected member of the National Academy of Sciences, the Institute of Medicine, and the American Academy of Arts and Sciences.

Dr. David Rasko is an Assistant Professor in the Department of Microbiology and Immunology and a member of the Institute for Genome Sciences. During his career he has developed expertise in comparative microbial genomics, bioinformatics and functional genomics. Dr. Rasko has led comparative genome sequencing and analysis projects for important human diarrheal pathogens, focusing on *Escherichia coli* and *Shigella* species as well as *Bacillus cereus* group isolates. He has developed comparative bioinformatics tools designed to characterize the genetic diversity in closely related bacterial isolates. Dr. Rasko was the first to publish a comparative genomic study that included a genome reference from a true commensal, each of the six diarrheagenic *E. coli* pathogenic variants (pathovars) as well as representatives of the urinary tract and avian derived *E. coli* to total 17 genomes. This resulted in the first description of the *E. coli* pangenome as "open" and identified a core gene set of ~2200 genes present in all *E. coli*. This comparative work has laid the framework for the continued functional study of the evolution of these pathogens, which has recently been expanded to include *Shigella* spp., as well as functional studies of these unique and conserved gene features.

Dr. James Musser following postdoctoral research at the Institute of Molecular Evolutionary Genetics, Pennsylvania State University, and residency training in Laboratory Medicine at the Hospital of the University of Pennsylvania, Dr. Musser joined the Department of Pathology, Baylor College of Medicine in Houston, Texas. He advanced through the academic ranks from 1991 to 1998, when he was promoted to Professor. Dr. Musser served as Chief, Laboratory of Human Bacterial Pathogenesis, National Institute of Allergy and Infectious Diseases from 1999-2003. He joined The Methodist Hospital Research Institute in 2005 as Co-Director and Executive Vice President. His research focuses on the molecular basis of host-pathogen interactions in group A *Streptococcus* and *Mycobacterium tuberculosis*. He serves on several editorial boards, has received many national and international honors and awards, and has published more than 300 research articles and book chapters.

Speaker Biographies

Dr. Marc W. Allard received his Ph.D. in biology in 1990 from Harvard University (Cambridge, MA). Dr. Allard was the Louis Weintraub Associate Professor of Biology (and Genetics) at George Washington University (Washington, DC) for 14 years from 1994 to 2008. He has had appointments to the Visiting Scientists Program both at the Federal Bureau of Investigation's Counterterrorism and Forensic Science Research Unit (CTFSRU) and in the Chem.-Bio. Sciences Unit (CBSU) for approximately 8 years, where he assisted in the anthrax investigations as well as in human genetics data-basing. Dr. Allard joined the Office of Regulatory Science and the Division of Microbiology in November 2008 and he is using DNA sequence information from the genomes of food borne pathogens to identify unique single nucleotide polymorphisms (SNPs) and whole proteins to rapidly identify the various strains of bacteria, particularly *Salmonella, E. coli, Shigella* and *Listeria*. Dr. Allard specializes in both phylogenetic analysis and bioinformatics methods, as well as the wet laboratory methods which generate this genetic information. mwallard@gmail.com, marc.allard@fda.hhs.gov. Recent papers on comparative genomics includes BMC Genomics 2012, 13:32; NEJM letter 2- 23- 2011.

Dr. Errol Strain is the Chief of the Biostatistics Branch in the Division of Public Health and Biostatistics at FDA/CFSAN. He received his Bachelor of Science degree in Biochemistry from Purdue University in 1998 and Ph.D. in Bioinformatics from North Carolina State University in 2006. Prior to joining the FDA in 2008, Dr. Strain worked for Becton Dickinson Technologies as a bioinformaticist in a stem cell therapy research group.

Dr. Gary Van Domselaar leads the bioinformatics research and development activities at the Public Health Agency of Canada's National Microbiology Lab (NM) and is an Adjunct Professor in the Departments of Medical Microbiology, Pharmacy, and Computer Science at the University of Manitoba. He obtained his PhD in Pharmaceutical Science in 2003 at the University of Alberta under Dr. David Wishart where he developed bioinformatics systems for bacterial genome annotation and analysis. He joined the NML in 2005 to lead the lab's bioinformatics section. In addition to supporting the research, surveillance, diagnostic, and outbreak response activities of the NML programs and its collaborators by processing, storing, managing, analysing, and interpreting biological data, his lab is actively involved in the development of cutting-edge computational tools, algorithms, and analytical methods including bioinformatics software development for bacterial annotation, analysis, and visualisation; bioinformatics for whole genome molecular epidemiology and outbreak response; analytical methods for vaccine discovery; and viral quasispecies sequence assembly and analysis. He is also a founding member and Associate Director of The Bioinformatics Organization, a website and on-line community promoting open source bioinformatics software development and open access to biological data and scientific publications.

Dr. Scott A. Jackson is a research microbiologist within the Division of Molecular Biology, in the Center for Food Safety and Applied Nutrition at FDA. He received his B.S. in Chemistry and Geology from the University of South Carolina in 1996; and is currently finishing his Ph.D. in microbial genetics from the Johns Hopkins University Biophysics Department. His dissertation Research involves the study of Catalytic Group I Introns as Mobile Genetic Elements. Since 2003, has served as a research microbiologist at FDA-CFSAN. Recently, he has established and developed a microarray-based genomics research group that is focused on the interrogation and understanding of the genomic diversity that exists among various classes of enteric pathogens.

Dr. Jim Ostell is the Chief of the Information Engineering Branch (IEB) of the National Center for Biotechnology Information (NCBI). Dr. Ostell earned a Ph.D. in molecular biology from Harvard University, developed commercial software for biotechnology, then helped create NCBI in 1988. As IEB Chief, Dr. Ostell has been responsible for designing, developing, building, and deploying the production resources at NCBI from its beginning including PubMed, GenBank, BLAST, Entrez, RefSeq, dbSNP, PubMed Central, dbGaP, and many others. In 2007 Dr. Ostell was inducted into the United States National Academies, Institute of Medicine, and made an NIH Distinguished Investigator in 2011.

Dr. Tatiana Tatusova possesses 20+ years' experience as a researcher and senior systems analyst, with 14 years devoted to algorithm development and applied program package evaluation for genome-related research. She has extensive experience in genome data analysis; interactive scientific Internet application and Web page elaboration; and conventional software including text and graphic editors and database management systems. For the last 13 years Dr. Tatusova has led a strong team of scientists and programmers who provided the infrastructural framework for the exchange and synthesis of the data. Dr. Tatusova received MS degree in Physics at Moscow State University in 1982; PhD in in Physics and Mathematics (Biophysics) at the same University in 1988; joined The National Center for Biotechnology Information (NCBI) in 1993, first as a contractor and later as a staff scientist.

Dr. Guy Cochrane is the head of the European Nucleotide Archive (ENA; http://www.ebi.ac.uk/ena/). The ENA provides a comprehensive repository for public nucleotide sequence data, attracting users from a multitude of research disciplines and serving as underlying data infrastructure for numerous bioinformatics services. Under Dr. Cochrane, the team has launched important new services, such as the Sequence Read Archive for raw data from next generation sequencing platforms and the CRAMtools sequence data compression platform (http://www.ebi.ac.uk/ena/about/cram_toolkit). In addition to the management of the twenty-strong team of biological curators, bioinformaticians and software engineers, he contributes editorial work to a number of journals and meetings and has been involved in standardisation activities in many areas of bioinformatics. He received his PhD in cancer cell and molecular biology from the University of East Anglia in 1999 and carried out post-doctoral work in the molecular biology of photoreception at Cambridge University prior to joining EBI.

Kevin McLoughlin is a Computational Biologist in the Pathogen Bioinformatics Group at Lawrence Livermore National Laboratory (LLNL), working with Tom Slezak. His research concerns analysis methods for microarrays, genomes and metagenome sequences. He leads the design and development of the LLNL Triangulation Tool, a unified system for pathogen detection, genotyping and functional characterization using array and sequence data. He is also completing a Ph.D. in Biostatistics at UC Berkeley, under the supervision of Terry Speed.

Dr. Stefan Niemann has studied Biology at the University of Bielefeld (Germany) where he obtained his diploma in 1992. From 1992-1996 he performed his PhD work in the department of Genetics at the University of Bielefeld. Since 1996 he worked as a senior scientist at the National Reference Laboratory for Mycobacteria (NRL), Research Center Borstel (Germany). In 2004 he gained his habilitation in Molecular Genetics and Microbiology, and became Assistant Professor (Privatdozent) at the University of Lübeck. Since 2006 he is head of the Molecular Mycobacteriology Group, NRL, Research Center Borstel. In 2010, he has been appointed president of the European Society of Mycobacteriology. Stefan is a specialist in molecular and pathobiological characterization of clinical *Mycobacterium tuberculosis* complex (MTBC) isolates. His research combines several fields of mycobacteriology ranging from molecular diagnostics, molecular epidemiology, genetics, genome analysis, microarray analysis and complex model systems. Actual research focuses on "rapid diagnostics", "epidemiology of tuberculosis", "determinants of resistance", "microevolution in clinical isolates", "global population structure", and "host pathogen interaction". One key research topic targets the in depth analysis of the complex host-pathogen that finally determines the outcome of infection. The link between the fascinating genomic variability of the pathogen and its association with antibiotic resistance, host-pathogen interaction and virulence is only incompletely understood and represents a challenging new topic of the research.

Dr. Minoru Kanehisa received a D.Sc. in physics from the University of Tokyo in 1976, Minoru Kanehisa worked in the Johns Hopkins University School of Medicine, the Los Alamos National Laboratory where he was one of the cofounders of GenBank, and the National Cancer Institute of the National Institutes of Health. Since 1987 he is Professor in the Institute for Chemical Research, Kyoto University, and since April 2001 he is Director of the newly established Bioinformatics Center of Kyoto University. He has also been professor at the Human Genome Center, Institute of Medical Science, University of Tokyo (1991-1995 and 2002-present). Other activities include: concurrent professorship in Kyoto University Graduate Schools of Biological Sciences (1987-present) and Pharmaceutical Sciences (2003-present), visiting professorship in National Institute for Basic Biology in Okazaki (1999-2001), Institute for Advanced Biosciences of Keio University (2001-2003), and the Boston University Bioinformatics Program (2005-present), presidents of the Japanese Society for Bioinformatics (1999-2003) and NPO Bioinformatics Japan (2009-present), principal investigator of the KEGG database project (1995-present), and many more (see Projects Archive).

Dr. Ole Lund has studied Mathematical Biology at Technical University of Denmark where he obtained his M. Sc. Degree in 1991. From 1991-1995, he earned his Ph.D. in Bioinformatics at Technical University of Denmark. Since 2007, he is Professor and group leader in Immunological Bioinformatics at Center for Biological Sequence Analysis, Technical University of Denmark. His research interests have been on different aspects of proteins such as their structure, post-translational modification, immunogenecity, and the dynamics of host-pathogen interactions. He has developed several bioinformatics methods for identification of T cell epitopes in pathogen organisms, and for classifying different HLA molecules functionally. Dr. Ole Lund's group are currently studying the correlations between protein function and antigenecity, and comparing genomes to find diagnostic antigens and virulence factors. He has also worked on modeling the dynamics of the immune system by Systems Biology approaches. Currently he is leader of bioinformatics at Center for Genomic Epidemiology, which is developing tools for real time analysis of whole genome sequence data for diagnostic and epidemiological use.

John McQuiston received a B.S. degree in 1988 in Recombinant Genetics from SUNY Fredonia in upstate New York, followed by a M.S. degree from Virginia Tech in 1992 in Veterinary Medical Sciences in molecular genetics of *Brucella* species. From 1992-1998, he worked as a technical specialist in recombinant vaccines of veterinary pathogens and molecular diagnostics at the Virginia Tech Center for Molecular Medicine and Infectious Diseases. In 1998, he accepted a research fellowship with what is currently the Enteric Diseases Laboratory Branch, of the Centers for Disease Control and Prevention (CDC) in Atlanta. Primarily his work has included the development of a molecular identification scheme for serotyping *Salmonella*. John earned a Ph.D. in evolutionary genetics of *Salmonella* from Emory University and until January, 2011, was a Research Microbiologist in the National *Salmonella* Reference Laboratory at CDC. Since January, 2011 he has been part of the Bacterial Special Pathogens Branch at CDC as the Team Lead for the Special Bacteriology Reference Laboratory. This Team identifies the rare and unusual pathogens of high consequence. It is also a major contributor to MicrobeNet.

Robert Stones has an underlying background in the biological sciences. Robert's first degree was in molecular biology & biochemistry at Durham University UK, moving into postgraduate studies in bioinformatics at York University UK. Robert has achieved success in bioinformatics research, with over 12 years of experience working in bioinformatics with both the US Food and Drug Administration, and the UK government science agency FERA (Food & Environment Research Agency). He is experienced in development of tools/systems for data storage, data visualization and high throughput data analysis. He has worked with a number of national and international collaborators - including partners from the US and EU. Examples of work areas include:

- Developing comparative genomic methods for the detection/analysis of foodborne bacteria
- Design of systems and analytical tools for mass spectroscopy technologies
- Development and implementation of software for rapidly interpreting NMR metabolomic data
- Proteomics software, as part of an EU funded consortium on TSE research
- Design and creation of software/databases to investigate allergens
- Other areas of interest, include next generation DNA sequence technologies, high throughput data processing,high performance computing and parallel computing architectures

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Ravi Jain has a combined 15 years of experience in bioinformatics, product development, program management and business development. He co-founded cBio and is currently its President and CEO. Prior to cBio, Dr. Jain was responsible for technical marketing at Cognia, a start-up bioinformatics software development firm. Before that, he developed point-of-care diagnostics at Biosite, now part of Alere. Dr. Jain started his career computationally designing drugs at Isis Pharmaceuticals. During graduate school, he founded and sold Redbooks Associates, a college materials publishing firm. Dr. Jain received his BS in Genetics from the University of California, Davis. He earned his PhD from UCLA.

Speaker Biographies

Lynn Bry, MD, PhD, FCAP is Director of the Center for Clinical and Translational Metagenomics (CCTM) at Brigham & Women's Hospital, and Associate Director at the Partners Center for Personalized Genetic Medicine. Dr. Bry is a Board-certified Pathologist and specializes in clinical laboratory testing for infectious agents and development of clinical-grade pipelines to support use of next generation sequencing (NGS) technologies for diagnostic purposes. Her research focuses on host-pathogen-commensal interactions in the GI tract. The CCTM supports investigators at Harvard-affiliated institutions and at other locations around the country. The Center includes a Microbiology Unit, co-directed by Dr. Andy Onderdonk, to perform quantitative culture of complex samples and identify isolates for functional studies, a gnotobiotic mouse facility for conducting in vivo functional studies in germfree or specifically-colonized mice, and a Computational Unit, directed by Dr. Georg Gerber, which assists with experimental design, development of pipelines to support research and diagnostic testing, and has developed novel algorithms to undertake time-series analyses of metagenomic datasets. The Center is funded in-part by the Harvard Digestive Diseases Center and Brigham & Women's Hospital. Her group also directs the Crimson Project that has implemented IT and logistical infrastructure that supports more than 100 groups at Harvard-affiliated institutions. Working with i2b2 (Informatics for Integrating Biology with the Bedside; http://www.i2b2.org), an NIH-funded National Center for Biomedical Computing, this infrastructure has enabled many large-scale genomic studies. This infrastructure is leveraged within the CCTM to enable real-time collection of infection control isolates and other human clinical materials that are used in research studies and clinical trials. Dr. Bry's group has received NIH funding through the National Library of Medicine to further integrate these capabilities within i2b2.

Dr. Julia Segre received her Ph.D. in 1996 from M.I.T. in the laboratory of Dr. Eric Lander, and the newly formed M.I.T. genome center. Dr. Segre joined the National Human Genome Research Institute of NIH in 2000 and was promoted to a senior investigator with tenure in 2007. Dr. Segre's laboratory utilizes high throughput sequencing and develops genomic algorithms to study bacterial outbreaks at the National Institutes of Health Clinical Center (NIH CC). Dr. Segre's research is based on active collaborations with the NIH Intramural Sequencing Center and the clinical departments of Infection Control, Microbiology, Dermatology, and Infectious Disease. Dr. Segre is a leader in the NIH Roadmap Human Microbiome Project.

Georg Gerber, MD, PhD, MPH is a computational biologist and physician specializing in clinical microbiology. He directs computational work at the newly created Brigham and Women's Hospital (BWH) and Harvard Center for Digestive Diseases (HDDC) Center for Clinical Metagenomics. The Center is a core facility within Harvard Medical School that supports a variety of basic, translational and clinical research projects investigating the role of the microbiome in human health and disease. Gerber's research is focused on developing and applying novel statistical machine learning and molecular technologies for understanding dynamic interactions between the microbiota and the host in infectious and inflammatory diseases. Gerber is also currently serving as Chief Resident in Clinical Pathology at BWH, where he will complete his residency training in July 2012. Prior to this, Gerber received his MD in 2009 from Harvard Medical School, and PhD in 2007 in Computer Science and Medical Engineering from the Massachusetts Institute of Technology (MIT) Laboratory for Computer Science and Artificial Intelligence. His doctoral research focused on developing novel algorithms for inferring genetic regulatory networks and gene expression programs from high-throughput biological data. He also holds an SM in Electrical Engineering and Computer Science from MIT, and an MPH in Infectious Diseases and a BA

in Pure Mathematics, both from UC Berkeley. Prior to returning to graduate school, Gerber worked in industry, holding several senior executive level positions supervising production and research and development of 3D graphics technologies for the film, television, video game, and Internet markets.

Dr. John Stelling is Co-Director of the WHO Collaborating Centre for Surveillance of Antimicrobial Resistance, based at the Brigham and Women's Hospital in Boston. Dr Stelling has worked since 1989 to support surveillance programmes for antimicrobial resistance in over 90 countries, and is developer of the WHONET software used for the management, analysis and sharing of microbiology laboratory data. Dr Stelling was a Medical Officer with the World Health Organization for three years in the Antimicrobial Resistance Unit of the Department of Communicable Diseases Surveillance and Response. Dr Stelling has an MPH from the Johns Hopkins School of Hygiene and Public Health and an MD from Harvard Medical School and completed an internship in family practice at San Francisco General Hospital.

Marion Koopmans, DVM, PhD completed her training in Veterinary Medicine at the Utrecht University, Veterinary Faculty. She worked as an associate professor at the same Faculty to become a specialist in Large Animal Internal Medicine and Nutrition. In parallel, she did a PhD in Veterinary Sciences (Virology; 1990), studying novel enteric viruses and their importance as pathogens for cattle. She continued to study enteric viruses during a fellowship and as visiting scientist at the Centers for Disease Control from 1991 until 1994. She returned to The Netherlands to become section chief of the enteric virus group at the National Institute of Public Health and the Environment (RIVM). She is coordinator of a European research and surveillance network on enteric viruses, and, since 2000, holds the chair of the Virology Division of the Diagnostic Laboratory for Infectious Diseases at RIVM. Her responsibilities include reference diagnostics, syndromic surveillance and emergency preparedness for viral diseases, including research aimed at improving the response capacity of a public health laboratory.

Dr. Peter Gerner-Smidt is a Danish M.D., D.M.Sc. with specialty in clinical microbiology. He is the chief of the Enteric Diseases Laboratory Branch in the Division for Foodborne, Waterborne and Environmental Diseases at Centers for Disease Control and Prevention in Atlanta, United States. He is chairman of the PulseNet International Steering committee and a member of the WHO Global Foodborne Infections network steering committee. Before moving to the United States in 2004, he was the Head of the Danish Reference Centre for Enteric Pathogens and *Listeria* at Statens Serum Institut in Copenhagen from 1995 and was involved in revamping and running national and European surveillance systems for bacterial foodborne infections. He was a member of the coordinating group for the Danish Zoonosis Centre and Danish representative in EnterNet, the European network for surveillance of Salmonella, VTEC and Campylobacter 1995- 2004 serving on the steering committee from 2001- 2004. He was the first coordinator of PulseNet Europe, the European network for molecular surveillance of foodborne infections. Dr. Gerner-Smidt is 58 years old and his research interests are the epidemiology, including subtyping and identification of foodborne, zoonotic and enteric bacterial pathogens. He has co-authored more than 100 papers in peer-reviewed scientific journals, the majority dealing with bacterial taxonomy, identification, epidemiology, and subtyping.

Speaker Biographies

Uwe Scherf, M.Sc., Ph.D., is the Deputy Director in the Division of Microbiology Devices in the Office of *In Vitro* Diagnostic Device Evaluation and Safety in FDA's Center for Devices and Radiological Health (CDRH). Prior to joining the U.S. Food and Drug Administration in 2004, Dr. Scherf was Senior Director for Genomics Research & Development at Gene Logic Inc., a genomic gene expression profiling company from 1999 to 2004. Before his work in industry, he worked for several years at National Cancer Institute/NIH and developed with Dr. John Weinstein and collaborators a gene expression database for the molecular pharmacology of cancer on the NCI 60 human cancer cell lines. During his stay at NCI, he also worked on targeting cancer therapy with recombinant fusion proteins. Dr. Scherf received his Ph.D. in Microbiology from the University of Marburg in Germany. He was voting member of the CLSI Area Committee on Molecular Methods from 2004- 2010, and a member of the Advisory Board of the School of Computational Sciences at the George Mason University in Virginia.

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