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Turning research data into knowledge for new discoveries

HIPAA, clinical data, and research:

I was on an NIH grant review panel this month and the number of 'translational medicine' grants applications was gratifying and somewhat daunting. It's great for someone who was in Pharma for 16 years to see a push focusing on clinical outcomes. What was apparent is that there is excellent academic (and industrial) research being done in this country. The pace of that research is accelerating, partly in thanks to rapid developments in high-throughput technologies for DNA sequencing, expression profiling, SNP detection, and other -omic methods.

Part of the review process was to ensure proper handling of Human Subjects and data. By and large, there were no issues with consent or ensuring that IRB approval and protocols were obtained and followed. But what about the data, especially as relates to working with clinical data? HIPAA (Health Insurance Portability and Protection Act) is a complex and well-enforced set of federal regulations protecting the privacy and security of patient information. The HIPAA privacy rule defines Protected Health Information (PHI) as data elements that can be used to link individual patients to their medical data and stipulates how these elements can be used in operational and research activities. The HIPAA security rule specifies measures to enforce the privacy requirements using electronic security, staff policies, and operational procedures.

The HIPAA privacy rule allows a limited dataset to be used for research. Ideally, this is in the form of a deidentified dataset, where all potential patient identifiers (PHI) are removed. There are 18 categories of identifiers designated as PHI some of which include: patient names, all geographic subdivisions smaller than state, including street address, city,

About the Company:

B-Tech, Ltd. provides contract research, consulting, and analytical services. We have worked extensively on the identification of differentially regulated genes using the Affymetrix and Illumina platforms, high-throughput DNA sequencing, SAGE and pathway analysis. We are also highly skilled in data integration, statistical analysis, and data presentation and visualization.

We are able to accommodate both large scale long-term projects as well as an individual experiment. All work is tailored to the needs of the researcher, and is a highly interactive process. In this way we ensure that the analytical methods will provide the best answer to the scientific questions being asked.

A typical analysis is completed within 2 weeks from receipt of data. If you have special needs, such as grant or meeting deadlines, we will do our best to accommodate your requests. Our work is affordable, professional, and presented in a format designed for the bench scientist.

county, postal codes, all elements of dates (except year) directly related to an individual (including birth date, encounter and treatment date, date of death), phone numbers, email addresses, IP or website addresses, social security numbers, health plan and insurance numbers, fingerprints, photographs, etc.

Realistically, this leaves out much information that can be of use for a clinical study. Looking at time course of treatment and trying to subset or stratify populations results in the requirement for creation of an identified dataset. Generation of genomic sequencing or genotyping data can also create a 'fingerprint' which may be legally sufficient to identify an individual. NCBI recently removed a large set of data over this concern, and access to the public database of genotype and phenotype data (dbGaP) requires authorization and adherence to the data security policy.

Each institution has a set of policies governing the use of patient data, and an IRB to ensure that these policies are enforced and protocols adhered to in the course of the research project or study. This is taken very seriously, as the penalties for misuse of patient data can be severe, and HHS actively enforces these rules.

A good data policy and IT systems can provide a high level of assurance that all rules are being followed, and access protocols are maintained. A secure and well-designed database and means of accessing those data can provide for those needs, as well as enhancing the ability of approved researchers to use the data. Rather than digging through notebooks, file directories, or giant Excel spreadsheets, a HIPAA-compliant database is centralized, secure, and backed up. Plus you can query the data intelligently with an easy to use "Google-like" interface, or through custom queries and reports.

B-Tech has experience in database design and clinical data management and analysis. We've done this for large Pharmaceuticals in clinical trials, academic collaborations, and Biotechnology companies. From consulting on how to implement a data management strategy to turnkey systems, we have a solution for your research needs.

- Brian

We currently perform contract research and support for several major universities, and we welcome reference checks. We have also worked closely with several top-tier pharmaceutical companies, which can also provide references.

About the Founder:

Brian Moldover, Ph.D. I have worked in bioinformatics since 1993, where I was a Research Fellow at NIH working in the Human Genome Project. Since then I spent 15 years working in the pharmaceutical industry for companies such as Warner-Lambert, Pfizer, Aventis, and Schering AG. I have held positions from Sr. Scientist through Vice-President of Global Research Computing. I have extensive knowledge of genomics and bioinformatics research, as well as significant business experience.

Because of my long industry experience, you can expect any work we perform to be done professionally, securely, and timely.

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