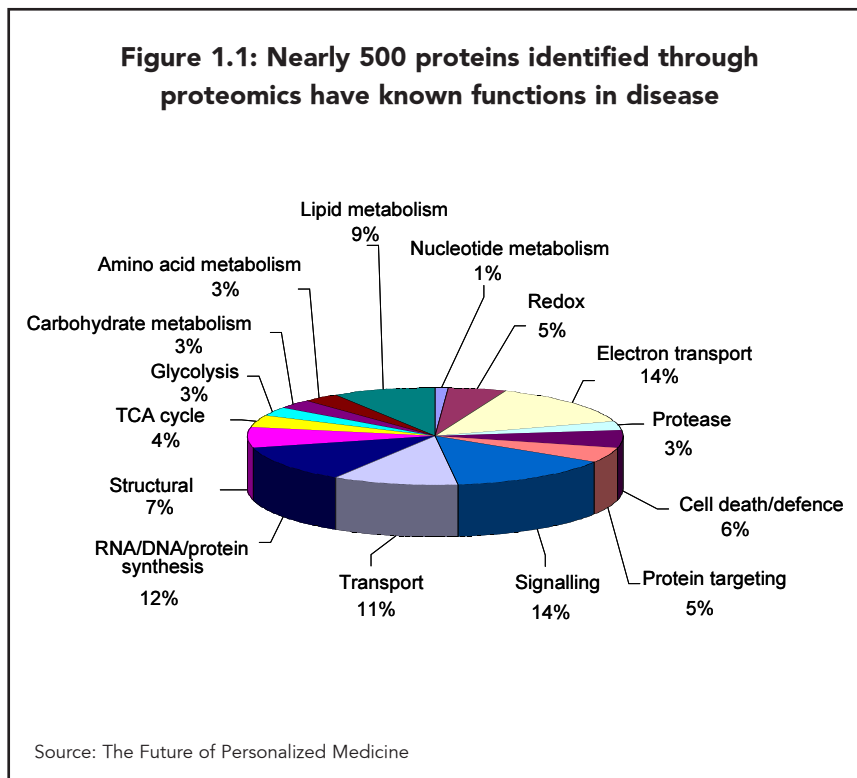


The Future of Personalized Medicine

The impact of proteomics on drug discovery and clinical trial design



'Personalized medicine could dramatically change the marketing environment as targeted therapies and diagnostics biomarkers play a greater role in determining treatment patterns. In place of blockbuster drugs, niche drugs will tap into small patient populations, resulting in physician education and direct-to-patient marketing becoming much more important to commercial success...'

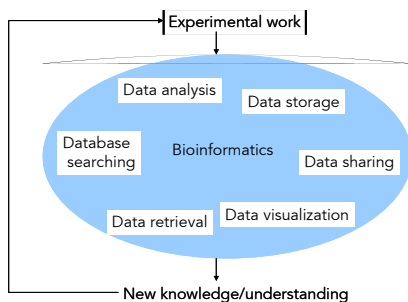
Identify how proteomic technologies will drive personalized medicine by improving attrition rates and drug discovery

with this NEW report...

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Figure 2.7: The role and scope of bioinformatics in proteomics research



Source: The Future of Personalized Medicine

"In the context of proteomics, bioinformatics encompasses both the analysis and presentation of raw data (such as 2-D gels, mass spectra etc), organising the information, querying databases to help identify unknown proteins and sharing the information with the scientific community. Ultimately, bioinformatics results feed back to direct further experimentation..."

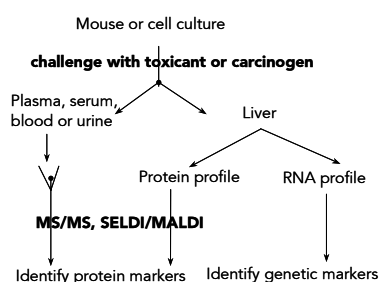
'Personalized Medicine: The impact of proteomics on drug discovery and clinical trial design' is a management report that analyses how proteomics will streamline drug development and lead to the more cost-effective development of niche personalized products of the future.

Proteomics promises lower R&D costs and the opportunities of new revenue streams through the identification of new drug targets in the treatment of diseases such as cancer and Alzheimer's. Use this report to identify the most important technologies, their applications in drug discovery and clinical trial design and the leading companies driving development of this exciting new area.

The pharmaceutical industry has so far been slow to take up proteomic technology and strategic alliances and acquisitions will be central to the pharmaceutical industry's uptake of proteomics. **This report identifies the key technologies that will enable pharmaceutical companies to develop new niche products, improve drug attrition rates, increase the speed of clinical development and target new drug markets.**

Key findings of the report

Figure 3.11: Strategies for analysis of toxicoproteomic data



Source: The Future of Personalized Medicine

"Two recent examples highlight the use of proteomics in the identification of toxicities and carcinogens. Researchers from the NCT Proteomics Program have harnessed the power of proteomics and genomics to screen liver and serum/plasma using MS/MS and SELDI/MALDI to identify biomarkers which are specifically altered by toxicants or carcinogenic drugs. Ultimately this research should produce useful markers and gain a better understanding of the mechanisms involved in toxicity and carcinogenesis..."

- Proteomics has the potential to reduce drug development time and drug attrition rates. If total development time is reduced by three years and the number of successful NDAs doubled, **R&D costs could be cut by as much as 30% per year.**
- **Companies investing in proteomics to target niche markets can reap considerable financial rewards** as exemplified by Gleevec (Novartis) and Herceptin (Roche) which generated around \$1bn in worldwide sales in 2003.
- There is a high unmet clinical need for early disease detection, such as in cancer and neurodegenerative diseases. **The development of diagnostic tools using "biomarkers" has the potential to result in better prognosis for patients** and to satisfy this unmet need.
- **More than \$700m has been invested in proteomics companies by venture capitalists and through IPOs** (Initial Public Offerings) in the last four years.
- As the main bottleneck in proteomics is the ability to analyze the colossal amount of data generated, **it is essential for companies to invest heavily in bioinformatics.**

The answers to your questions



“The flow of genetic material is mirrored by three disciplines of biological research: genomics (characterisation of DNA), transcriptomics (mRNA) and proteomics (proteins). There is physiological regulation at each stage of this flow, for example, not all DNA is transcribed into mRNA at any one time, and mRNA may be degraded before it can be translated into protein...”

- What evidence is there that supports the impact of proteomics on pharmaceutical market productivity?
- Which companies have already invested in proteomics and what strategic alliances have been formed during the last 5 years?
- What role will proteomics have in the development of personalized medicine now and in the future?
- What is the role of bioinformatics in proteomics and what are the relative strengths and weaknesses of “free” and searchable databases on the worldwide web?
- What examples are there of the success of proteomics in the diagnosis and treatment of cancer, neurodegenerative diseases and cardiovascular diseases?

Why you should order your copy today

Table 3.10: New proteomic targets

Protein class	Protein target	Disease target	Source
Capase	CARD	Cancer	Damiano JS & Reed JC, 2004
HDAC inhibitors	PXD101*	Cancer	CuraGen, 2004
HMGCoA		HIV	Reeves & Beckerbauer, 2002
Kinase	PI3K/Akt phosphorylation	AD	Ward, 2004
SIRT1		AD and PD	Araki, 2004
Serine proteases	u-PA	Cancer	Corvas, 2001
Serotonin 3B receptor		Schizophrenia	Davis, 1999
Tyrosine Kinases	PDK1, PKB (Akt)	Cancer	Harris, 2003
	NS3-4A	hepatitis C	Vetex, 2000
Tyrosine Phosphatase	GBM	Cancer	AGY Therapeutics 2002

* In phase I clinical development; GBM - glioblastoma multiforme; u-PA - urokinase plasminogen activator; CARD - Capase-associated recruitment domain

Source: The Future of Personalized Medicine

“Proteomics has begun to identify a number of new targets for small molecule drug development and it is estimated that there are more than 700 products in various phases of clinical development but substantial challenges remain to effectively optimize these proteins as drug targets and diagnostic tools. The table above highlights some of the recent developments for new target-based therapies derived from the application of proteomics...”

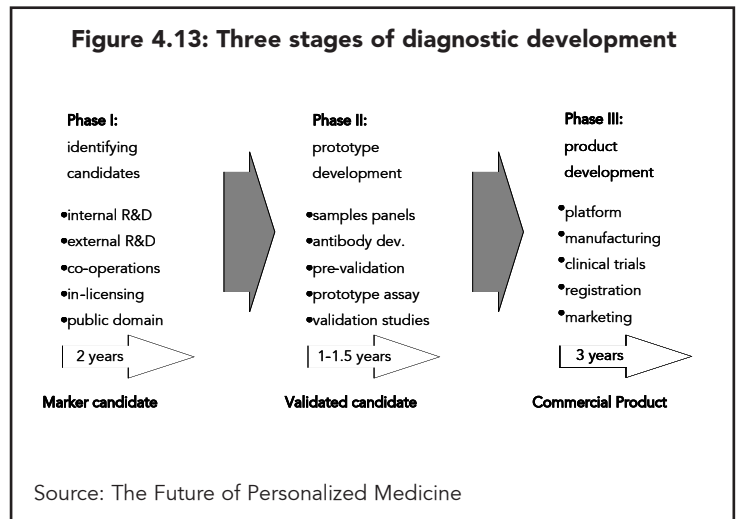
- **Determine the most effective strategy of applying proteomics to all stages of the drug to development process** to improve productivity and reduce R&D expenditure.
- **Evaluate and learn from the acquisitions and strategic alliances** formed between big pharmaceuticals and proteomics-based companies over the last five years.
- **Discover where proteomics has already impacted the identification of new drug targets** and biomarkers for diagnosis screening.
- **Highlight the potential long term cost savings** associated with the integration of proteomic technologies in the pharmaceutical industry.
- **Assess the freely available technologies and databases** which will enable new players to harness the power of proteomics in the drug development process.

Sample information from the report

CHAPTER 4: PROTEOMIC APPLICATIONS IN CLINICAL TRIAL DESIGN AND PERSONALIZED MEDICINE

Developments in proteomic technologies such as mass spectrometry (MS), SELDI and protein arrays have enabled researchers to profile proteins in normal and diseased tissues to help identify multiple biomarkers or protein signatures that are indicative of disease, drug response and safety. These are often more sensitive and selective than single biomarkers and have considerable potential in the development of non-invasive diagnostic tests.

However, this is only the first step in the development of diagnostic tests which can be used as well-defined clinical endpoints in clinical trials. The tests must be reproducible and specific, ideally 99.9% accurate rather than 95% sensitive as many of the current studies suggest.



Diagnostics is a booming industry generating over \$29bn sales in 2003 with approximately \$6bn of sales being generated from immunodiagnostics. There is a great need for new tests to reach the market as there has been a slow down in the numbers approved in the last 10 years. However, the development of diagnostics can be almost as protracted as drug development and any new tests identified now may take several years to reach the market.

For many diseases there is a high unmet clinical need due to poor diagnosis e.g. cancer and neurodegenerative, however the development of diagnostic tools using "biomarkers" could significantly improve the percentage of patients diagnosed at the earlier stage of a disease ultimately resulting in better prognosis. In addition, the regular analysis of "biomarkers" could help determine at what stage a treatment should be initiated or terminated, helping to provide a cost-effective process for medical or surgical intervention. Proteomics can enable drugs with low general efficacy to be used by people whose protein expression suggests they are more suited to a particular medication - the beginning of personalized medicine.

Herceptin (trastuzumab), the anti-cancer agent from Roche/Genentech, is an important example where diagnostic biomarkers have been used to enable a drug to reach the market when the drug is only clinically effective in a sub-set of the patient population. Herceptin is a monoclonal antibody that targets HER-2 (human epidermal growth factor receptor), a protein which is over-expressed in approximately 25%-30% of metastatic breast cancers. HER-2 over-expression is strongly correlated with poor prognosis.

Importantly, the FDA has only approved Herceptin for first-line use in combination with Taxol (Bristol Myers Squibb) or as a monotherapy in HER2 protein over-expressing metastatic breast cancer patients. Thus, it targets a sub-set of breast cancer patients - the first example of personalized medicine.

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- The human genome versus the proteome
 - Identification of human genome
 - Applications to proteomics
- The relationship between the proteome and the genome
 - The genome
 - Proteins
 - From genes to proteins
 - Proteomics

CHAPTER 2: PROTEOMIC TECHNOLOGIES

- Laboratory methods used in proteomics
 - Separation techniques
 - Identification techniques
 - Interactions techniques
 - Separation techniques
 - Identification techniques
 - Protein-protein interaction techniques
- Automation
 - Pre-fractionation
 - Separation
 - Identification
 - Complete proteomics solutions
- Bioinformatics and databases
 - Data Analysis
 - Databases
 - Laboratory information management systems (LIMS)

CHAPTER 3: PROTEOMIC APPLICATIONS IN DRUG DISCOVERY

- Optimizing the R&D process
- Early selection of efficacious and non-toxic drug targets
 - Toxicoproteomics
 - Pharmacoproteomics
- Accelerating the discovery of new targets for therapeutic candidates
 - Therapeutic proteins

- Protein targets
- Mining the proteome is an alternative approach for drug discovery

CHAPTER 4: PROTEOMIC APPLICATIONS IN CLINICAL TRIAL DESIGN AND PERSONALIZED MEDICINE

- Development of new biomarkers
 - Biomarkers as clinical endpoints
 - Responders and non-responders
 - Patients with adverse reactions
 - Patients in different stages of a disease, or other subsets of patients
 - Monitor clinical responses in new and comparator drugs - allowing potential strategic alliances
 - Patients with disease resistance
 - Niche markets
- Application of biomarkers in different therapy areas
 - Oncoproteomics
 - Application in the diagnosis of: ovarian cancer, prostate cancer, breast cancer and esophageal cancer
 - Neuroproteomics
 - Application in the diagnosis of: Alzheimer's diseases and amyotrophic lateral sclerosis (ALS)
 - Cardioproteomics
 - Cardiovascular markers
 - Respiratory markers
 - Application in organ transplantation
- Post-marketing applications of biomarkers

CHAPTER 5: PHARMACEUTICAL AND PROTEOMIC COMPANY ALLIANCES

- Recent collaborations and alliances of pharmaceutical and proteomic based companies

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Chapter: Reformulation for Leading Drugs: Case Studies 2000-2005
Report: Achieving Market Dominance Through Reformulation
- Strategic review**
Moreover, AstraZeneca has a wide range of cardiovascular products to compensate for patent expiry of Zestril including the long-acting ACE inhibitor.
Chapter: Reformulation for Leading Drugs: Case Studies 2000-2005
Report: Achieving Market Dominance Through Reformulation
- Strategic review**
Results announced in 2001 show that nizatidine therapy can help patients prevent or reduce weight gain. Although the data is preliminary, co-administe...
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Report: Achieving Market Dominance Through Reformulation
- Marketing strategies for reformulated products**
Fast-acting tablet; once-daily formulation) with concomitant media to inform patients and physicians about hypertension and cardiovascular diseases with the objective to increase awareness and recognition of reformulated Adalat products.
Chapter: Marketing and Branding for Pharmaceutical Reformulations
Report: Achieving Market Dominance Through Reformulation
- Reformulation alliance portfolio**
Kroll entered into an agreement with Ethvoharm to develop a

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