Personalized Medicine, Targeted Therapeutics and Companion Diagnostic Market to 2019 - Strategic Analysis of Industry Trends, Technologies, Participants and Environment

Description: This is a comprehensive account of the market size, segmentation, key players, SWOT analysis, influential technologies, and business and economic environments. The report is supported by over 360 tables & figures over 393 pages. The personalized medicine (global & USA) market is presented as follows:

- By Company (e.g., Qiagen, AFFYMETRIX, ATOSSA GENETICS, NODALITY, deCode /Amgen, CELERA, MYRIAD)
- By Segment (Targeted therapeutics, Companion Diagnostics, Liquid Biopsies)
- By Sub-market ( Companion diagnostic, targeted cancer therapeutic, medical technology, pharmacogenomics, consumer genomics, molecular diagnostics, liquid biopsy)
- By Therapy (Cancer, Cardiovascular, Infectious Disease)

Key Opinion Leaders that contributed to interview questions within the report include:
- Iain D. Miller, PhD, MBA, Founder & CEO, Healthcare Strategies Group
- Stephen Finn, MBBS, PhD, Associate Professor, Cancer Molecular Diagnostic Laboratory, Consultant Histopathologist and Head of Histopathology, St James's Hospital and Trinity College Dublin, Ireland
- Ronald Przygodzki, MD, Director, Genomic Medicine Implementation at U.S. Department of Veterans Affairs, Washington DC
- Elaine Kenny, PhD, Founder, Elda Biotech, Dublin 2, Ireland
- Chad Clark, Co-President and Chief Operating Officer, Precision for Medicine
- Tobias Guen nel, PhD, Principal, Biomarker and IVD Analytics, Precision for Medicine
- David Parker, PhD, Vice President, Integrated Market Access, Precision for Medicine
- Deborah Phippard, PhD, Vice President, Research, Precision for Medicine
- Judi Smith, MS, Vice President, In Vitro Diagnostics Regulatory and Quality, Precision for Medicine

A wealth of financial data & business strategy information is provided including:

- Company financials, sales & revenue figures
- Business Model Strategies for Diagnostic, Pharmaceutical and Biotechnology Companies
- Business Model Strategies for Providers. Provider Systems and Academic Medical Centres
- Business Model Strategies for Payers & Governments
- Private and Public Funding and Personalized Medicine Reimbursement
- Revisions to Current Payment Systems and intellectual property
- How to Gain Market Penetration in the EU
- Cost-effectiveness and Business Value of Personalized Medicine
- Therapeutics and Companion Diagnostics (e.g., BRAC Analysis, Oncotype Dx, KRAS Mutations)
- Comprehensive account of company product portfolios & kits

SWOT, Economic & Regulatory Environment specifics include:

- Key strengths, weaknesses and threats influencing leading player position within the market
- Technologies driving the market (e.g., New-Generation Sequencing Technologies, Ultra-High Throughput Sequencing)
- Top fastest growing market segments and emerging opportunities
- Top pharmaceutical companies within the IPM by market share and revenue
- Comprehensive product portfolios, R&D activity and pipeline therapeutics
- M&A activity and future strategies of top personalized medicine pharmacos
- Personalized Medicine Regulation (USA, UK, Germany, France, Spain, Italy)
- CE-marked Personalized Medicine/Diagnostic Tests
- FDA Advances in Personalized Medicine Regulation

This report highlights a number of significant pharmacos and gives details of their operations, products, financials and business strategy.
What you will gain:

- An in-depth understanding of the global personalized medicine market and it’s environment
- Current market facts, figures and product lines of key players in the industry
- Emerging trends in key markets such as the US, UK, Germany and France
- Knowledge of how the personalized medicine market will integrate into the global healthcare market
- Technical insights into new generation sequencing technologies and ultra-high throughput sequencing
- Updates on bioinformatics, high throughput systems, genetic analysis kits, companion diagnostics and future technologies
- FDA approved pharmacogenetic tests and recognized biomarkers
- Information on key government and regulatory policies
- Strategies on how to adapt and restructure current business models to this industry

This report tackles key concerns to the personalized medicine market such as:

- Lack of regulatory policy and legislation in the US and Europe
- Reimbursement schemes and payers concerns
- Transition of investigational diagnostic assays and therapeutics to clinical practice
- Direct to consumer (DTC) test kits and implications for the public

Who should read this report?

- Pharmaceutical, biotechnology and diagnostic companies (CEOs, VPs, Business Development, C-Suite) with an interest in personalized medicine
- Industry professionals and business strategists will discover key information to propel their policies
- Investors will gain inside information to dominant players in the industry and future forecasts
- Scientists will get a business perspective and industry insight into how scientific breakthroughs influence the market environment

This report will tell you if the companies mentioned are:

- Strong, competitive players
- Pooling their resources for specific growth and therapeutic areas
- Investing strategically in R&D
- Have a history of strategic M&A activity

This detailed report is supported with 360 figures and tables over 393 pages and profiles the main pharmacos in personalized medicine.

Benefits of Investing in our Cutting-Edge Reports:

- Clients receive complementary content* with mid-level and enterprise wide licences
- Post-sale complementary consultation with senior expert analyst is included
- Use of tables and figures in your own reports and presentations is permitted
- Each report provides straight-talking strategic analysis & sector intelligence
- All reports are updated each quarter to give you the most up-to-date information

WE WANT TO MAXIMIZE YOUR BUSINESS POTENTIAL
* Subject to terms & conditions negotiated prior to sale
Contents:

1.0 Executive Summary
1.1 Objectives of Report
1.2 Scope of Study
1.3 Data Sources and Methodology
1.4 Key Findings and Observations
1.4.1 CYP2C9 and VKORC1 mutations and Warfarin Response
1.4.2 KRAS Mutations
1.4.3 Herceptin® and Breast Cancer
1.4.4 BRACAnalysis®
1.4.5 Oncotype Dx Test
1.4.6 Public and Private Funding for Personalized Medical Research
1.4.7 New Business Model Required for Personalized Medicine
1.4.8 Cost-effectiveness and Business Value of Personalized Medicine
1.4.9 Personalized Medicine Market
1.4.10 Personalized Medicine Oncology Therapeutics & Diagnostics Market
1.4.11 Personalized Medicine Cardiovascular Therapeutics Market
1.4.12 PharmacoGenomics/PharmacoGenetics Market Analysis
1.4.13 Liquid Biopsy Market Analysis

2.0 Introduction and Background
2.1 Genetics Explained in Five Minutes
2.1.1 Why is the Central Dogma of Molecular Biology Important in Personalized Medicine?
2.1.2 Genetic Mutations Explained
2.1.3 What is the Difference between Genotype and Phenotype?
2.1.4 Why do we Need to Look at Genetic Diversity with Respect to Personalized Medicine?
2.2 Introduction to Personalized Medicine
2.3 Pharmacogenetics
2.4 How Personalized Medicine Monitoring can Reduce Adverse Drug Reactions
2.5 Pharmacogenetic Study Challenges
2.6 Pharmacogenomics
2.7 Applications of Pharmacogenomics
2.7.1 Pharmacogenomics: Improving the Safety of Medications
2.7.1.1 Adverse Drug Reactions
2.7.1.2 Pharmacogenomics: Improving the Efficacy of Therapeutics
2.7.2 Vioxx Disaster Could have been Prevented with Personalized Medicine
2.8 Pharmacogenetic Analysis
2.8.1 Single Base Primer Extension
2.8.2 Primer Based Base Extension
2.8.3 Hybridization Based SNP Analysis
2.8.4 Ligation Based Approach
2.8.5 New-Generation Sequencing Technologies
2.8.6 Ultra-High Throughput Sequencing
2.9 Companion Diagnostics
2.9.1 Companion Diagnostic Deals
2.10 Selected Personalized Medicine Drugs by Biomarker and Indication
2.11 Selected Personalized Medicine Test/Kit According to Therapeutic and Indication
2.12 Targeted Cancer Therapy
2.13 What Percentage of Cancer Patients Could be Treated by Targeted Therapy?
2.14 Liquid Biopsies
2.14.1 CANCER-ID Project
2.14.2 Challenges for Liquid Biopsies
2.15 Tumor Genetic Heterogeneity
2.15.1 Introduction
2.15.2 Clonal Evolution – How Phylogenetic Analysis is Aiding Personalized Medicine
2.15.3 Therapeutic Resistance
2.15.4 Tumor Immunogenicity
2.15.5 Tumor Neo-Antigen Production
2.15.6 Sampling Tumor Heterogeneity with Liquid Biopsies
2.15.7 How Does Tumor Heterogeneity Impact Personalized Medicine?
2.15.8 Summary
2.16 How Next Generation Functional Diagnostics is Helping Personalized Medicine

3.0 Personalized Medicine Targeted Therapeutics and Associated Companion Diagnostics
3.1 CYP2C9 and VKORC1 mutations and Warfarin Response
3.2 HLA-B*5701 and Abacavir Response
3.3 KRAS Mutations
3.3.1 Erbitux
3.3.2 Vectibix
3.4 Herceptin® and Breast Cancer
3.5 BRACAnalysis®
3.5.1 Comprehensive BRACAnalysis®
3.5.2 BRACAnalysis® Rearrangement Test (BART)
3.5.3 Single Site BRACAnalysis®
3.5.4 Multisite 3 BRACAnalysis®
3.6 Oncotype Dx Test
3.7 Therascreen® EGFR RGQ PCR Kit
3.8 Therascreen KRAS RGQ PCR System
3.9 Therascreen® IDH1/2 test
3.10 THxID™ -BRAF Kit
3.11 Cobas® EGFR Mutation Test (Roche)
3.12 Prolaris Prostate Cancer Test
3.13 ALK and Non-Small Cell Lung Cancer
3.13.1 ALK-Fusion Testing
3.13.2 VYSIS ALK Break Apart FISH Probe Kit
3.13.3 VENTANA ALK (D5F3) CDx Assay
3.13.4 ResponseDx: Lung™

4.0 Personalized Medicine and Integration into the Healthcare System
4.1 The Personalized Medicine Coalition
4.2 Personalized Medicine and the Healthcare System
4.3 Clinical Application of Personalized Medicine
4.4 Clinical Laboratory Improvement Amendments-Certified Laboratory of Genomic Pathology

5.0 Private and Public Funding and Personalized Medicine Reimbursement
5.1 International Research and Development Personalized Medicine Activity
5.1.1 Publically Funded Personalized Medicine Research
5.1.2 Privately Funded Personalized Medicine Research
5.2 Popular Biological Targets/Pathways in Pharmacogenetic/Pharmacogenomic Research
5.3 Equitable Payer Reimbursement
5.3.1 Molecular Diagnostic Payments in Personalized Medicine
5.3.1.1 RVU-CPT-ICD Coding System
5.3.2 Laboratory Service Payments in Personalized Medicine
5.3.3 Revisions to Current Payment System
5.4 Biorepositories and Biobanks
5.5 Intellectual Property and Personalized Medicine

6.0 European Personalized Medicine Market – Payments and Investment
6.1 Personalized Medicine and The European Market
6.2 European Investment in Personalized Medicine
6.3 Overview of Reimbursement Policies in Europe
6.4 Gaining Market Penetration in the EU
6.5 Personalized (Stratified) Medicine Regulation and Reimbursement in the UK
6.5.1 Precision Medicine Catapult
6.6 CE-marked Personalized Medicine/Diagnostic Tests in the UK
6.7 Personalized Medicine Regulation in Germany
6.8 Personalized Medicine Regulation in France
6.8.1 R&D UNICANCER France
6.9 Personalized Medicine Regulation in Spain
6.10 The Personalized Medicine Regulation in Italy
6.11 Challenges of Future Personalized Medicine Development in Europe

7.0 Personalized Medicine - Business Model Analysis
7.1 New Business Model Required for Personalized Medicine
7.2 Business Model Strategies for Diagnostic, Pharmaceutical and Biotechnology Companies
7.3 Business Model Strategies for Providers, Provider Systems and Academic Medical Centres
7.4 Business Model Strategies for Payers
7.5 Business Model Strategies for Governments
7.6 Introduction of Non-Health Companies to the Personalized Medicine Market
7.7 Change to the Big Pharma Business Model
7.8 Cost-effectiveness and Business Value of Personalized Medicine
7.9 Comparative Effectiveness Research in Personalized Medicine
7.10 Reimbursement, Coverage and Payment Policy

8.0 Personalized Medicine Main Industry Players
8.1 23andMe
8.1.1 Key Products
8.2 Abbott Laboratories
8.2.1 Abbott Molecular Inc.
8.3 Admera Health (GENEWIZ)
8.3.1 Products and Kits
8.3.2 PGxOne
8.3.3 OncoGxOne
8.3.4 OncoGxOne Plus
8.3.5 FloraCheck
8.3.6 EGFR & KRAS Clinical Sequencing
8.4 Agena Biosciences (Sequenom)
8.4.1 MassARRAY System
8.4.2 Acquisition of Sequenom’s Bioscience Business by Agena Biosciences
8.5 Affymetrix
8.5.1 Products and Kits
8.6 Agendia
8.7 Alere
8.8 Amgen Inc.
8.8.1 Vectibix (panitumumab)
8.8.2 Blinatumomab (Blincyto)
8.8.3 Rilotumumab
8.9 Astex Pharmaceuticals
8.9.1 Products and Kits
8.10 AstraZeneca
8.10.1 Iressa
8.10.2 Tagrisso AZD9291 (Osimertinib)
8.11 Atossa Genetics
8.11.1 Mammary Aspirate Specimen Cytology Test (MASCT™)
8.11.2 ForeCYTE Breast Health Test (SM)
8.11.3 ArgusCYTE Breast Health Test (SM)
8.11.4 FullCYTE Breast Health Test
8.12 Becton Dickinson
8.12.1 Key Products
8.13 BioMerieux
8.13.1 Key Products
8.14 BioRad
8.15 Bristol-Myers Squibb Company
8.15.1 Erbitux (cetuximab)
8.15.2 OPDIVO (nivolumab)
8.15.3 Yervoy (ipilimumab)
8.16 Cancer Genetics
8.16.1 Key Products
8.17 Celera Corporation (Quest Diagnostics)
8.17.1 ViroSeq® HIV-1 Genotyping System
8.17.2 ViroSeq® HIV-1 Integrase Assay
8.17.3 ViroSeq® HCV Assay
8.17.4 ViroSeq® HBV Assay
8.17.5 Cystic Fibrosis Genotyping Assay
8.17.6 LDL-S GGE® Test
8.17.7 HDL-S GGE® Test
8.17.8 KIF6-StatinCheck TM Genotype Test
8.17.9 LPA-AspirinCheck TM Genotype Test
8.17.10 9p21-EarlyMICheckTM Genotype Test
8.17.11 AlleleSEQR® HLA PCR/Sequencing Kits
8.17.12 m2000® RealTime PCR System
8.17.13 CEGA -16™ Instrument
8.18 Celldex Therapeutics
8.19 Cepheid
8.20 Claritas Genomics
8.20.1 Products and Kits
8.20.2 Clarifocus Exome for Pediatric Neurology
8.21 CuraGen
8.22 deCode Genetics (Amgen)
8.22.1 deCodeT2 Genetic Test
8.22.2 deCODE Breast Cancer™
8.22.3 deCODE Prostate Cancer™
8.22.4 deCODE AF™
8.22.5 deCODE Glaucoma™
8.22.6 deCODE MI™
8.22.7 deCODE Complete™
8.22.8 deCODE Cancer™
8.22.9 deCODE Cardio™
8.22.10 deCODE Services
8.23 EDP Biotech
8.24 ELDA BioTech
8.25 Eisai
8.26 Foundation Medicine
8.26.1 FoundationOne
8.26.2 FoundationOne Heme
8.27 HaloDx
8.28 Human Longevity Inc (Cypher Genomics)
8.29 Ikonisys
8.30 Illumina
8.30.1 Illumina HiSeq 2000/1000
8.30.2 Genome Analyzer IIX
8.30.3 Illumina MiSeq
8.30.4 Illumina HiScanHQ
8.30.5 Illumina HiScan and iScan Array
8.31 Intergenetics
8.32 Genelex
8.32.1 You Script™
8.33 Johnson & Johnson (Janssen)
8.34 LabCorp (Covance)
8.34.1 Covance and M2Gen Partnership
8.35 Integrated Oncology
8.35.1 Main Products
8.36 Merck & Co., Inc.
8.36.1 Main Products
8.37 MDx Health
8.38 MolecularMD Corporation
8.39 Monogram Biosciences
8.40 Myriad
8.40.1 Key Products
8.40.2 COLARIS®/COLARIS AP®
8.40.3 MELARIS®
8.40.4 PANEXIA®
8.40.5 OnDose®
8.40.6 PREZEON™
8.40.7 THERAGUIDE® 5FU
8.40.8 Prolaris®
8.41 Nanorstring Technologies
8.42 Nodality
8.42.1 Products and Kits
8.43 Novartis
8.43.1 Novartis Molecular Diagnostics
8.43.2 Novartis Oncology
8.44 Orion Genomics
8.45 Oxford BioTherapeutics
8.46 Pfizer
8.46.1 Pfizer Merger with Allergan
8.46.2 Pfizer’s Oncology Strategy
8.46.3 Pfizer’s Personalized Healthcare Strategy
8.47 Qiagen
8.47.1 Key Products
8.47.2 Genotyping Products
8.47.3 QIAsymphony Platform
8.48 Roche
8.49 Roche Diagnostics
8.49.1 Roche Acquisition of Ventana Medical Systems
8.49.2 Roche’s Personalized Medicine Strategy
8.49.3 Avastin (Bevacizumab)
8.49.4 Herceptin (Trastuzumab)
8.49.5 Kadcyla (Trastuzumab emtansinum)
8.49.6 Perjeta (Pertuzumab)
8.49.7 MabThera/Rituximab
8.49.8 Tarceva
8.50 Sanofi
8.50.1 Sanofi’s Personalized Medicine Strategy
8.51 Siemens Healthcare
8.51.1 Companion Diagnostic Development at the Siemens Clinical Laboratory (SCL)
8.52 Takeda
8.52.1 Takeda’s to Discover Therapeutic Targets in the Microbiome
8.52.2 Millennium: The Takeda Oncology Company
8.53 Thermo Fisher Scientific
8.53.1 Thermo Fisher’s Personalized Healthcare Strategy
8.53.2 Thermo Fisher’s Involvement in the NCI-MATCH Trial
8.54 Transgenomic
8.55 Vertex Pharmaceuticals
8.55.1 Orkambi (lumacaftor/ivacaftor)
8.55.2 Kalydeco (ivacaftor)

9.0 Personalized Medicine Market Analysis
9.1 Companion Diagnostic and Targeted Therapeutic Market
9.1.1 Global Oncology Therapeutic Market
9.1.2 Targeted Therapeutics – Oncology
9.1.3 Top Ten Companies in Oncology Drug Sales to 2020
9.1.4 Top Five Oncology Drugs to 2020
9.1.5 Global Oncology Market by Cancer Type
9.1.6 Oncology Targeted Therapeutics Market Analysis to 2020
9.1.7 Companion Diagnostic Assays – Oncology
9.2 Cardiovascular Targeted Therapeutics Market to 2019
9.2.1 Cardiovascular Companion Diagnostics Market to 2020
9.3 Infectious Disease Targeted Therapeutics Market to 2019
9.3.1 Infectious Disease Diagnostic Assay Market to 2019
9.4 Global Personalized Medical Technology Market
9.5 Global Personalized Medicine Sub-Market Growth
9.6 PharmacoGenomics/PharmacoGenetics Market Analysis to 2019
9.7 Molecular Diagnostics Market to 2020
9.8 Consumer Genomics Market
9.9 Liquid Biopsy Market to 202
9.10 Major Player Profit Margin Analysis
9.11 Select Market Participant Case Study Analysis
9.11.1 23andme
9.11.2 Affymetrix
9.11.3 Astex Pharmaceuticals
9.11.4 Atossa Genetics
9.11.5 Celera (Quest Diagnostics)
9.11.6 Celldex Therapeutics
9.11.7 deCode Genetics (Amgen)
9.11.8 Illumina
9.11.9 Genelex
9.11.10 Myriad
9.11.11 Nodality
9.11.12 Qiagen
9.11.13 bioMerieux

10.0 Strengths and Advantages of Personalized Medicine
10.1 Sequencing of the Human Genome in 2000
10.2 Improving Patient Care and Reducing Side Effects
10.3 Personalized Medicine will Reduce Healthcare Costs
10.4 FDA Advances in Personalized Medicine Regulation
10.5 Advancing Technologies
10.5.1 Next Generation Sequencing
10.6 Industry Investing in Pharmacogenomics
10.7 Consumer Genomics and POC Market
10.8 Oncology a Driving Force of Personalized Medicine

11.0 Restraints of the Personalized Medicine Market
11.1 Lack of Sufficient Regulation
11.2 Lack of Sufficient Genotypic Linkage Studies to Disease Phenotype
11.3 Reimbursement Issues

12.0 Personalized Medicine and Regulatory Policies
12.1 Regulation by the Centres for Medicare and Medicaid Services (CMS) and US Food and Drug Administration (FDA)
12.2 Genetic Information Non-discrimination Act (GINA)
12.3 FDA Advancements on Genetic Testing Approval
12.4 FDA- New Models to Assess Gene Therapy Safety
12.5 FDA- Companion Diagnostics
12.6 FDA - Partnership in Applied Comparative Effectiveness Science (PACES) Initiative
12.7 National Institutes of Health Genetic Testing Registry

13.0 Final Summary and Future Perspectives
13.1 Re-cap of Personalized Medicine in 2015

14.0 Interviews with Key Opinion Leaders

Iain D. Miller, PhD, MBA, Founder & CEO, Healthcare Strategies Group
Stephen Finn, MBBS, PhD, Associate Professor, Cancer Molecular Diagnostic Laboratory, Consultant Histopathologist and Head of Histopathology, St James's Hospital and Trinity College Dublin, Ireland
Ronald Przygodzki, MD, Director, Genomic Medicine Implementation at U.S. Dept Veterans Affairs, Washington DC
Elaine Kenny, PhD, Founder, Elda Biotech, Dublin, Ireland
Chad Clark, Co-President and Chief Operating Officer, Precision for Medicine
Tobias Guennel, PhD, Principal, Biomarker and IVD Analytics, Precision for Medicine
David Parker, PhD, Vice President, Integrated Market Access, Precision for Medicine
Deborah Phippard, PhD, Vice President, Research, Precision for Medicine
Judi Smith, MS, Vice President, In Vitro Diagnostics Regulatory and Quality, Precision for Medicine

List of Tables

Table 2.1: Glossary: Common Terms Used in Genetics and Personalized Medicine
Table 2.2: Types of Genetic Markers used as Biomarkers in Personalized Medicine
Table 2.3: Genetic Disease Associated with the Ashkenazi Jew Population
Table 2.4: Disease Types Associated with Specific Populations
Table 5.1: Public Funding Bodies for Pharmacogenetic/Pharmacogenomic Research
Table 5.2: American Companies Involved in Pharmacogenomics/genetics Drug Development & Diagnostics
Table 5.3: European Companies Involved in Pharmacogenomics/genetics Drug Development & Diagnostics
Table 5.4: North American Companies Involved in Pharmacogenomics/genetics Services
Table 5.5: European/Other Companies Involved in Pharmacogenomics/genetics Services
Table 5.6: American Companies Involved in Pharmacogenomics/genetics Tools Kits & Software
Table 5.7: European Companies Involved in Pharmacogenomics/genetics Tools Kits & Software
Table 5.8: North American Companies with Minor interest in Pharmacogenomics/genetics
Table 5.9: European/Other Companies with Minor interest in Pharmacogenomics/genetics
Table 5.10: North American Companies with Minor interest in Pharmacogenomics/genetics
Table 5.11: European/Other Companies with Minor interest in Pharmacogenomics/genetics
Table 5.12: Large US Companies with Investment into Pharmacogenomics/genetics
Table 5.13: Large European Companies with Investment into Pharmacogenomics/genetics
Table 5.14: Large Japanese Companies with Investment into Pharmacogenomics/genetics
Table 5.15: Top Ten Biological Areas of Interest in Pharmacogenetics/genomics
Table 5.16: Top International Pharmacogenetic/Pharmacogenomic Research Institutions
Table 5.17: Top European Pharmacogenetic/Pharmacogenomic Research Institutions
Table 6.1: Variation of Reimbursement Policies for HER2 & KRAS Testing in Europe
Table 6.2: Pharma Providing Subsidization of Personalized Medicine Tests in Europe
Table 6.3: Challenges Within Personalized Medicine Market in Europe
Table 6.4: Function of the European network for Health Technology Assessment Organisation
Table 6.5: European network for Health Technology Assessment (EUnetHTA) Partners
Table 6.6: European network for Health Technology Assessment (EUnetHTA) Associates
Table 6.7: Diagnostics Guidance Assessment by the National Institute Health Clinical Excellence
Table 6.8: Current Diagnostics Guidance in Development by the Diagnostics Access Program, UK
Table 6.9: Published Diagnostics Guidance by the Diagnostics Access Program, UK
Table 6.10: Medical Technologies Guidance Assessment by NICE
Table 6.11: Published Medical Technologies Guidance by NICE
Table 6.12: Published Medical Technologies Guidance in Development NICE
Table 6.13 Precision Medicine Catapult Tools to Aid Market Entry
Table 6.14 Key Challenges to Personalized Medicine
Table 6.15: Strategic Objectives of French Comprehensive Cancer Centers within UNICANCER
Table 6.16: Key Challenges to Personalized Medicine
Table 6.17: Personalized Medicine - Translation into Medical Applications
Table 7.1: Major Market Trends in Personalized Medicine
Table 7.2: Collaboration Strategies Required between Industry, Payers & Governments
Table 7.3: Business Model Recommendations: Diagnostic, Pharma& Biotech Companies
Table 7.4: Business Model Recommendations: Providers. Provider Systems & Medical Centres
Table 7.5: Business Model Recommendations for Payers
Table 7.6: Business Model Recommendations for Governments
Table 7.7: Non-Healthcare Companies with Potential to enter the Personalized Medicine Market
Table 7.8: Hurdles of Personalised Medicine with Respect to Cost-Effectiveness
Table 8.1: 23andMe Disease Risk Genetic Test Panel
Table 8.2: 23andMe Carrier Status Genetic Test Panel
Table 8.3: 23andMe Drug Response Genetic Marker Test Panel
Table 8.4: 23andMe Genetic Traits Test Panel
Table 8.5: Admera Health Commercial Drug List that are Covered by the PGxOne Assay
Table 8.6: Admera Health PGxOne Gene & Variant List, Therapeutic Area & Endorsing Agency
Table 8.7: Patent Listing of Affymetrix Array technology
Table 8.8: Patent Listing of Affymetrix Genotyping Technology
Table 8.9: Patent Listing of Affymetrix Expression and Profiling Technology
Table 8.10: Product Overview of Affymetrix
Table 8.11: Microarray Products by Affymetrix
Table 8.12: Affymetrix Research Services Laboratory (ARSL) Premier Services
Table 8.13: Genetic Applications of Axiom® Technology by Affymetrix
Table 8.14: Amgen's Product Pipeline
Table 8.15: Selected Programs in Pivotal Trial (Phase III) or Development, Amgen
Table 8.16 Advantages of Astex Pharmaceuticals
Table 8.17: Astex Pharmaceuticals Pipeline Portfolio
Table 8.18: Astex Pharmaceuticals Pipeline Portfolio Funded Completely by Partner Companies
Table 8.19: Range of Small Molecule Therapeutics Available from Astex Pharmaceuticals
Table 8.20: Biomarkers by Cancer Type Offered by bioMerieux
Table 8.21: Cancer Genetics Product Portfolio Flow Cytometry Based Assays
Table 8.22: Cancer Genetics Product Portfolio FISH Based Assays
Table 8.23: Cancer Genetics Product Portfolio Molecular Diagnostics Based Assays
Table 8.24: Cancer Genetics Product Portfolio Complete™ Test Program
Table 8.25: Select One Clinical Trial Services
Table 8.26: Panel of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Mutations Screened for in Celera Cystic Fibrosis Genotyping Assay
Table 8.27: Genetic Tests Available from BHL/Celera
Table 8.28: Panel of BHL Clinical Diagnostic Tests
Table 8.29: Features of the m2000® RealTime PCR System by Celera
Table 8.30: Potential Business Partnerships of Celldex Therapeutics
Table 8.31: Cepheid Product Portfolio to 2019 in the US
Table 8.32: Cepheid Product Portfolio to 2019 Internationally
Table 8.33: Claritas Genomics Genetic Test Portfolio, by Gene
Table 8.34: Genetic Diagnostic Tests Available from deCode Genetics
Table 8.35: Type 2 Diabetes risk range and distribution according to continental ancestry as Determined by deCODET2 Genetic Test
Table 8.36: Genetic Mutations Identified by the deCODE MI™ Test in a European Population
Table 8.37: Genetic Mutations Identified by the deCODE MI™ Test in an East Asian Population
Table 8.38: Disease States that are Included in the deCODE Complete™ Genetic Screen
Table 8.39: Panel of Diseases Screened for in the deCODE Cancer™ Test
Table 8.40: Panel of Cardiovascular Diseases in the deCODE Cardio™ Test
Table 8.41: deCODE Genetics Genotyping and Sequencing Service
Table 8.42: deCODE Genetics Data Management, Protection and Storage Service
Table 8.43: deCODE Genetics Sequence Inputation and Data Analysis Service
Table 8.44: FoundationOne Current Gene List
Table 8.45: FoundationOne Heme Gene List
Table 8.46: Foundation Medicine Company-Sponsored Clinical Trials
Table 8.47: Illumina Core Technologies
Table 8.48 Illumina Core Technology Applications
Table 8.49 Illumina Instrument Product Portfolio
Table 8.50 Illumina Assay Product Portfolio
Table 8.51 Illumina HiSeq 2500/1500 Performance Parameters
Table 8.52 Illumina HiSeq 2000/1000 Performance Parameters
Table 8.53 Genome Analyzer Ilx Performance Parameters
Table 8.54 Illumina MiSeq Product Specifications
Table 8.55 Illumina HiScanHQ Product Specifications
Table 8.56 Illumina HiScan and iScan Array Product Applications
Table 8.57 Illumina HiScan and iScan Array Kits
Table 8.58 Clinical Applications of Diagnostic Tests Offered by Intergenetics
Table 8.59 Genetic Test Panel Available from Genelex for Research Institutions and Clinical Trials
Table 8.60 Panel of Genetic Screens Available from Genelex
Table 8.61 Drug Sensitivity Screens Available from Genelex
Table 8.62 Integrated Oncology Cancer Test Portfolio
Table 8.63 Biopharma Merck's Key Product Range
Table 8.64 Molecular MD Biomarker Assays by Platform and Method Used
Table 8.65 MolecularMD Test Panels by Next Generation Sequencing, Molecular Targeted Therapy Management and Pathway Analysis
Table 8.66 MolecularMD Companion Diagnostic Development Capabilities
Table 8.67 Monogram Biosciences HIV Genotypic and Phenotypic Test Portfolio
Table 8.68 Predictive Genetic Tests Available from Myriad
Table 8.69 Services offered with BRACAnalysis® Testing from Myriad
Table 8.70 Advantages of BRACAnalysis® Testing
Table 8.71 COLARIS® Test Range by Myriad
Table 8.72 COLARIS AP® Test Range by Myriad
Table 8.73 MELARIS® Test Range by Myriad
Table 8.74 Personalized Medicine Tests from Myriad
Table 8.75 OnDose® Testing Procedure from Myriad
Table 8.76 Nanostring Technologies nCounter Workflow Platform Product Portfolio
Table 8.77 Pre-Clinical, Clinical and Commercial Applications of SCNP by Nodality
Table 8.78 Novartis Oncology Key Personalized Medicine Drug Targets
Table 8.79 Orion Genomics Collaboration and Commercial Agreements
Table 8.80 Oxford BioTherapeutics Main Technologies in Cancer Targeting
Table 8.81 Oxford BioTherapeutics Product Pipeline Portfolio by Development Stage
Table 8.82 Pfizer Key Branded Products
Table 8.83 Pfizer Oncology Targets and Technologies
Table 8.84 Pfizer Early Stage Pipeline Oncology Portfolio
Table 8.85 Qiagen Timeline of Events, 1994-2012
Table 8.86 Range of Product Groups from Qiagen
Table 8.87 Qiagen Genotyping Products for Sample Collection, stabilization and Storage
Table 8.88 Qiagen Genotyping Products for Genomic DNA Isolation and Purification
Table 8.89 Qiagen Genotyping Products for PCR Based Genotyping Analysis
Table 8.90 Qiagen Products for Genotyping Analysis
Table 8.91 Qiagen Genotyping Products for PCR Detection
Table 8.92 Qiagen Assays for Genetic Analysis
Table 8.93 Qiagen Pyrosequencing-Based Genetic Analysis Products
Table 8.94 Specifications and Features of Qiagen's QIAsymphony and QIAsymphony RGQ
Table 8.95 Roche's Personalized Medicine Products by Patient Stage
Table 8.96 ThermoFisher Scientific Clinical Assays and Technologies for Personalized Healthcare
Table 8.97 Transgenomic Technology Platforms
Table 8.98 Transgenomic Partnerships and Collaborations
Table 9.1 Global Market for Oncology Drugs by Geography/Country, Through 2020
Table 9.2 Top Ten Companies in Oncology Sales Forecast 2013 – 2020
Table 9.3 Top Five Oncology Drugs, Through 2020
Table 9.4 Submarkets within the Personalized Medicine Technology Market
Table 9.5 Global Market for Liquid Biopsy by Region (North America, Europe, RoW), to 202
Table 9.6 Operating Profit Margin Analysis for Selected Players in the PM Industry
Table 9.7 Personalized Medicine Industry Segments and Companies Analysed
Table 9.8 Drug Classes Investigated by 23andMe Using Genome Wide Association Studies
Table 9.9 Acquisition Profile of Affymetrix
Table 9.10 Genetic Applications of Axiom® Technology by Affymetrix
Table 9.11 Diversified Business Units of Affymetrix
Table 9.12 Affymetrix AgBio Microarray Portfolio
Table 9.13 Celera (Quest Diagnostics) Historic Operating (Loss) Laboratory Services & Products
Table 9.14 Diagnostic Test Product Manufactured by BHL/Celera & Distributed by Abbott
Table 9.15 Cellldex Therapeutics R&D Expenses ($ Thousands) 2010-20
Table 9.16 Price Listing of Genelex Familial Genetic Tests
Table 9.17 Myriad - Core Business Decisions and Impact on Industry
Table 9.18 Future Test Portfolio of Myriad
Table 9.19 Nodality's Single Cell Network Profiling (SCNP) for Drug Discovery & Validation
Table 9.20 BioMerieux Immunodiagnostic Product Portfolio
Table 9.21 BioMerieux Microbiology Product Portfolio
Table 9.22 BioMerieux Molecular Diagnostic Product Portfolio
Table 10.1 Strengths, Drivers and Advantages of Genotyping Techniques
Table 10.2 Strengths, Drivers and Advantages of Personalized Medicine Market
Table 11.1 Restraints of Personalized Medicine Market
Table 12.1 Summary of Clinical Laboratory Improvement Amendments (CLIA)
Table 12.2 Clinical Laboratory Improvement Amendments (CLIA) Testing Categories
Table 12.3 Test Features required prior to FDA Approval and Clearance
Table 12.4 Impact of Genetic Information Non-discrimination Act (GINA) on Healthcare Companies & Health Plans
Table 12.5 Impact of Genetic Information Non-discrimination Act (GINA) on US Employers, employment agencies, labor organizations and training programs
Table 12.6 FDA Commitment to the Personalized Medicine Industry
Table 12.7 Objectives of the 'Advancing Regulatory Science at FDA: A Strategic Plan'
Table 12.8 FDA Policy & Guidance Recommendations
Table 12.9 Implementation Strategy of the FDA to Advance Regulatory Science - Develop better Models of Human Adverse response
Table 12.10 Implementation Strategy of the FDA to Advance Regulatory Science - Identify and evaluate biomarkers and endpoints that can be used in non-clinical & clinical evaluations
Table 12.11 Implementation Strategy of the FDA to Advance Regulatory Science - Use and develop computational methods and in silico modelling
Table 12.12 National Institutes of Health Genetic Testing Registry Test Information
Table 13.1 2015 Targeted Therapeutic and Companion Diagnostic FDA Drug Approvals

List of Figures
Figure 2.1: DNA, Histones and Chromosomes
Figure 2.2: DNA is Composed of Four Nucleotide Bases
Figure 2.3: The Central Dogma of Molecular Biology – How DNA Encodes Protein
Figure 2.4: How Research, Technology, Regulation, Clinical Implementation and Legislation Integrates into Personalized Medicine
Figure 2.5 Identification of Good and Non-Responders in a Patient Population
Figure 2.6 Pharmacodynamic and Pharmacokinetic Examples of Drug Targets and Drug metabolism in Pharmacogenomics
Figure 2.7 Flow Diagram of Pharmacogenetic Analysis
Figure 2.8: Primer Based Base Extension in Pharmacogenetics
Figure 2.9: Genetic Mutation Detection by Hybridization
Figure 2.10: Ligation based SNP Detection
Figure 2.11 New-Generation Sequencing: Pyrosequencing
Figure 2.12 Number of Companion Diagnostic Deals Signed on a Yearly Basis
Figure 2.13 Percentage of Cancer Patients with Genetic Mutations that could be Treated by Targeted Therapy
Figure 2.14 Detection of Cell Free cfDNA in Cancer Patients – Timeline of Events
Figure 2.15 Cell Free Nucleic Acids Present in Blood from Cancer Patients
Figure 2.16 Detection of cfDNA and its Alterations in Different Forms of Cancer
Figure 2.17 CANCER-ID Consortium Global Location of Collaborators
Figure 2.18 CANCER-ID Consortium Work Package Outline
Figure 2.19 Use of Tumor Educated Blood Platelet mRNA Expression Levels in Liquid Biopsies
Figure 2.20 Types of Tumor Heterogeneity- Intratumor, Interpatient, Inter/intrametastatic
Figure 2.21 Tumor Clonal Evolution as Depicted in a Phylogenetic Tree
Figure 2.22 Mechanisms of Resistance to Targeted Therapies (Vemurafenib, Crizotinib, EGFR MAbs, EGFR TKIs, Imatinib)
Figure 2.23 Next Generation Functional Diagnostics in Cancer
Figure 3.1: Warfarin Metabolism and Response
Figure 3.2: Percentage Frequency of CYP2C9 and VKORC1 mutations in Caucasian, African-American and Asian Populations
Figure 3.3: Anti-EGFR Therapy and KRAS Mutations
Figure 3.4: KRAS and BRAF Genetic Tests Available from Asuragen
Figure 3.5: Global Incidence and Mortality of Cancer in Women
Figure 3.6: Cancer Deaths in Women, Globally according to Cancer Type
Figure 3.7: Estimated Age-Standardised Incidence Rate per 100,000 of Breast Cancer Globally
Figure 3.8: HER2 Testing Algorithm for Breast Cancer
Figure 3.9: HER2 Cellular Signalling
Figure 3.10: Herceptin – Mechanism of Action
Figure 3.11: BRCA Mutation Increases the Risk of Breast and Ovarian Cancer
Figure 3.12: Proactive Cancer Management and Preventative Measures Reduces the Risks of Developing BRCA-associated Breast and Ovarian Cancer
Figure 3.13: ALK Cellular and Nuclear Signalling Pathway
Figure 3.14: ALK-Positive Cancers by Fusion Protein, ALK expression & Point Mutations
Figure 4.1: Integration of Multiple components for a Personalized Medicine Healthcare System
Figure 4.2: Workflow Diagram illustrating Clinical Laboratory Improvement Amendments-Certified Laboratory of Genomic Pathology
Figure 4.3: Hypothetical Flow Diagram of a Patient & the Genomic Pathology Clinical Laboratory
Figure 5.1: Personalized Medicine Scheme Interaction with Industry, Regulatory Bodies and Funding Agencies
Figure 5.2: Number of Publically Funded Pharmacogenetic and Pharmacogenomic Research Teams Internationally
Figure 6.1: Adverse Drug Reactions are the Fourth Leading Cause of Death
Figure 6.2: Efficacy Rate of Major Disease Types with Standard Treatment
Figure 6.3: The In Vitro Diagnostic Market in Europe
Figure 6.4: Organization of the European network for Health Technology Assessment (EUnetHTA)
Figure 6.5: Key Differences in Reimbursement Policy Approaches for Oncology Diagnostics and Therapeutics in Europe and the US
Figure 6.6: Flow Diagram of the German Healthcare System and Key Agencies
Figure 6.7: German Reimbursement Arrangement, Process and Implications
Figure 6.8: Key Information about UNICANCER France
Figure 6.9: Strategic Flow Diagram of UNICANCER France and its Operations
Figure 7.1: Annual Healthcare Expenditure for Major Industrial Nations
Figure 7.2: Estimated Life Expectancy from Birth for Major Industrialized Countries
Figure 8.1 Flow Diagram of Celera CEGA-16™ Instrument for Cystic Fibrosis Gene Analysis
Figure 9.46  Affymetrix Revenue by Product Division – Consumables, Instruments 2010-2014  
Figure 9.47  Affymetrix Core Product Sales – Gene Expression, Genetic Analysis & Clinical Applications and Life Science Reagents, 2011-2014  
Figure 9.48  Affymetrix Revenue Derived from Outside the US, 2009-2014  
Figure 9.49  Affymetrix Revenue Derived from the US, 2009-2014  
Figure 9.50  Affymetrix Net Loss, 2009-2014  
Figure 9.51  Affymetrix Research and Development Funding, 2009-2014  
Figure 9.52  Affymetrix Revenue Generated within USA (Percentage) 2010-2014  
Figure 9.53  Astex Pharmaceuticals Priority Pipeline Products SGI-110 and AT13387 by Indication, Clinical Phase and Timeline  
Figure 9.54  Astex Pharmaceuticals Revenue Generated 2008-2020  
Figure 9.55  Astex Pharmaceuticals Net Income 2009-20  
Figure 9.56  Atossa Genetics Total Revenue (US$) 2012-2014  
Figure 9.57  Atossa Genetics Revenue (US$) Generated by MASCT Sales and ForeCYTE & ArgusCYTE Diagnostic Testing  
Figure 9.58  Atossa Genetics Percentage Revenue Generated by MASCT Sales and ForeCYTE & ArgusCYTE Diagnostic Testing  
Figure 9.59  Quest Diagnostics Revenue ($ Billions) 2008-2014  
Figure 9.60  Quest Diagnostics Operating Revenue ($ Billions) 2008-2014  
Figure 9.61  Quest Diagnostics Net Income ($ Billions) 2008-2014  
Figure 9.62  Celera (Quest Diagnostics) Historic Revenue Generated 2008-2010  
Figure 9.63  Celera (Quest Diagnostics) Historic Gross Margin Generated 2008-2010  
Figure 9.64  Celera (Quest Diagnostics) Historic Revenue Generated– Laboratory Services and Products 2008 -2010  
Figure 9.65  Celera (Quest Diagnostics) Historic Revenue (%) Generated by Distribution Agreement with Abbott 2008-2010  
Figure 9.66  Celera (Quest Diagnostics) Historic Research and Development Spending 2008-2010  
Figure 9.67  deCode Genetics Historic Net Loss Incurred 2004-2008  
Figure 9.68  Illumina Revenue Generated ($ Billions) 2010-2014  
Figure 9.69  Illumina Net Income Generated ($ Billions) 2010-2014  
Figure 9.70  Myriad Revenue Generated 2007-2014  
Figure 9.71  Operating Income Generated by Myriad 2007-2014  
Figure 9.72  Myriad Revenue Generated by Molecular Diagnostic Testing and Pharmaceutical and Clinical (Companion Diagnostic) Services, 2012-2014  
Figure 9.73  Future Molecular Diagnostic Pipeline of Myriad  
Figure 9.74  Customer Profile of Qiagen – Percentage of Net Sales 2014  
Figure 9.75  Qiagen Global Net Sales 2007-2014  
Figure 9.76  Qiagen Operating Income 2007-2014  
Figure 9.77  Qiagen Global Net Income 2007-2014  
Figure 10.1: Percentage Oncology (Lung, Colorectal, Breast, Prostate) Patients Undergoing Next Generation Sequencing Testing in the US, 2018  
Figure 10.2: Pipeline and On-market Oncology (Lung, Breast, Colorectal, Prostate) Therapeutics Directed Against Specific Mutations, 2013
Ordering:

Order Online - [http://www.researchandmarkets.com/reports/3617035/](http://www.researchandmarkets.com/reports/3617035/)

Order by Fax - using the form below

Order by Post - print the order form below and send to

  Research and Markets,
  Guinness Centre,
  Taylors Lane,
  Dublin 8,
  Ireland.
Fax Order Form
To place an order via fax simply print this form, fill in the information below and fax the completed form to 646-607-1907 (from USA) or +353-1-481-1716 (from Rest of World). If you have any questions please visit http://www.researchandmarkets.com/contact/

Order Information
Please verify that the product information is correct and select the format(s) you require.

Product Name: Personalized Medicine, Targeted Therapeutics and Companion Diagnostic Market to 2019 - Strategic Analysis of Industry Trends, Technologies, Participants and Environment
Web Address: http://www.researchandmarkets.com/reports/3617035/
Office Code: SCH3W9V9

Product Formats
Please select the product formats and quantity you require:

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic (PDF) -</td>
<td></td>
</tr>
<tr>
<td>Single User:</td>
<td>USD 3800</td>
</tr>
<tr>
<td>Electronic (PDF) -</td>
<td></td>
</tr>
<tr>
<td>1 - 10 Users:</td>
<td>USD 7600</td>
</tr>
<tr>
<td>Electronic (PDF) -</td>
<td></td>
</tr>
<tr>
<td>Enterprise Wide:</td>
<td>USD 11000</td>
</tr>
</tbody>
</table>

Contact Information
Please enter all the information below in BLOCK CAPITALS

Title: [ ] Mr  [ ] Mrs  [ ] Dr  [ ] Miss  [ ] Ms  [ ] Prof
First Name: __________________________ Last Name: __________________________
Email Address: * __________________________
Job Title: __________________________
Organisation: __________________________
Address: __________________________
City: __________________________
Postal / Zip Code: __________________________
Country: __________________________
Phone Number: __________________________
Fax Number: __________________________

* Please refrain from using free email accounts when ordering (e.g. Yahoo, Hotmail, AOL)
Payment Information

Please indicate the payment method you would like to use by selecting the appropriate box.

☐ Pay by credit card: You will receive an email with a link to a secure webpage to enter your credit card details.

☐ Pay by check: Please post the check, accompanied by this form, to:
Research and Markets,
Guinness Center,
Taylors Lane,
Dublin 8,
Ireland.

☐ Pay by wire transfer: Please transfer funds to:
- Account number: 833 130 83
- Sort code: 98-53-30
- Swift code: ULSBIE2D
- IBAN number: IE78ULSB98533083313083
- Bank Address: Ulster Bank,
  27-35 Main Street,
  Blackrock,
  Co. Dublin,
  Ireland.

If you have a Marketing Code please enter it below:

Marketing Code: ____________________________

Please note that by ordering from Research and Markets you are agreeing to our Terms and Conditions at http://www.researchandmarkets.com/info/terms.asp