Partnering Terms & Agreements in Diagnostics.
Report description

The **Diagnostics Partnering Terms and Agreements** report provides comprehensive understanding and unprecedented access to the diagnostic partnering agreements entered into by the worlds leading healthcare companies.

The report provides a detailed understanding and analysis of how and why companies enter diagnostic partnering deals. The majority of deals are development stage whereby the licensee obtains a right or an option right to license the licensors diagnostic technology or product candidates. These deals tend to be multicomponent, starting with collaborative R&D, and commercialization of outcomes.

Understanding the flexibility of a prospective partner’s negotiated deals terms provides critical insight into the negotiation process in terms of what you can expect to achieve during the negotiation of terms. Whilst many smaller companies will be seeking details of the payments clauses, the devil is in the detail in terms of how payments are triggered – contract documents provide this insight where press releases and databases do not.

This report contains a comprehensive listing of all diagnostics partnering deals announced since January 2007, including financial terms where available, including over 2,900 links to online deal records of actual diagnostics partnering deals as disclosed by the deal parties. In addition, where available, records include contract documents as submitted to the Securities Exchange Commission by companies and their partners.

The initial chapters of this report provide an orientation of diagnostics dealmaking and business activities. Chapter 1 provides an introduction to the report, whilst chapter 2 provides an overview of the trends in diagnostics dealmaking since 2007, including details of average headline, upfront, milestone and royalty terms.

Chapter 3 provides a review of the leading diagnostics deals since 2007. Deals are listed by headline value, signed by bigpharma, most active bigpharma, and most active of all biopharma companies. Where the deal has an agreement contract published at the SEC a link provides online access to the contract.

Chapter 4 provides a comprehensive listing of the top 50 bigpharma companies with a brief summary followed by a comprehensive listing of diagnostics deals, as well as contract documents available in the public domain. Where available, each deal title links via Weblink to an online version of the actual contract document, providing easy access to each contract document on demand.

Chapter 5 provides a comprehensive and detailed review of diagnostics partnering deals signed and announced since January 2007, where a contract document is available in the public domain. The chapter is organized by stage of development at signing, deal type (collaborative R&D, co-promotion, licensing etc), and specific therapy focus. Each deal title links via Weblink to an online version of the deal record and where available, the contract document, providing easy access to each contract document on demand.

The report also includes numerous tables and figures that illustrate the trends and activities in diagnostics partnering and dealmaking since 2007.

In conclusion, this report provides everything a prospective dealmaker needs to know about partnering in the research, development and commercialization of diagnostics technologies and products.
Key benefits

Diagnostics Partnering Terms and Agreements provides the reader with the following key benefits:

- In-depth understanding of diagnostic deal trends since 2007
- Analysis of the structure of diagnostic agreements with numerous real life case studies
- Comprehensive access to over 2,900 actual diagnostic contracts entered into by the world’s biopharma companies
- Detailed access to actual diagnostic contracts enter into by the leading fifty bigpharma companies
- Insight into the terms included in a diagnostic agreement, together with real world clause examples
- Understand the key deal terms companies have agreed in previous deals
- Undertake due diligence to assess suitability of your proposed deal terms for partner companies

Report scope

Diagnostics Partnering Terms and Agreements is intended to provide the reader with an in-depth understanding of the diagnostic trends and structure of deals entered into by leading companies worldwide.

Diagnostics Partnering Terms and Agreements includes:

- Trends in diagnostic dealmaking in the biopharma industry since 2007
- Analysis of diagnostic deal structure
- Case studies of real-life diagnostic deals
- Access to over 2,900 diagnostic contract documents
- The leading diagnostic deals by value since 2007
- Most active diagnostic dealmakers since 2007
- The leading diagnostic partnering resources

In Diagnostics Partnering Terms and Agreements, the available contracts are listed by:

- Headline value
- Stage of development at signing
- Deal component type
- Specific therapy target

Each deal title links to online deal records of actual diagnostics partnering deals as disclosed by the deal parties. In addition, where available, records include contract documents as submitted to the Securities Exchange Commission by companies and their partners.
The **Diagnostics Partnering Terms and Agreements** report provides comprehensive access to available contract documents for over 2,900 diagnostic deals. Analyzing actual contract agreements allows assessment of the following:

- What are the precise diagnostic rights granted or optioned?
- What is actually granted by the agreement to the partner company?
- What exclusivity is granted?
- What is the payment structure for the deal?
- How are sales and payments audited?
- What is the deal term?
- How are the key terms of the agreement defined?
- How are IPRs handled and owned?
- Who is responsible for commercialization?
- Who is responsible for development, supply, and manufacture?
- How is confidentiality and publication managed?
- How are disputes to be resolved?
- Under what conditions can the deal be terminated?
- What happens when there is a change of ownership?
- What sublicensing and subcontracting provisions have been agreed?
- Which boilerplate clauses does the company insist upon?
- Which boilerplate clauses appear to differ from partner to partner or deal type to deal type?
- Which jurisdiction does the company insist upon for agreement law?

**Number of pages:**

The report is comprised of 1,350 pages.
Executive Summary

Welcome to the Partnering Terms and Agreements in Diagnostics report.

The report provides a detailed understanding and analysis of how and why companies enter diagnostic partnering deals. The majority of deals are development stage whereby the licensee obtains a right or an option right to license the licensors diagnostic technology or product candidates. These deals tend to be multicomponent, starting with collaborative R&D, and commercialization of outcomes.

There are also a significant number of late stage and marketed diagnostic product partnering deals announced each year, where the licensor is seeking a partner to manufacture, supply, market, distribute or co-promote the product to enhance market coverage. This is particularly prevalent in diagnostics as partners often rely on diagnostic specialists to manufacture, distribute and supply products to the market.

A relatively unique characteristic of diagnostic partnering is the amount of acquisition activity relative to the total number of partnering deals, especially in recent years. It would appear that many biopharma companies have sought to acquire rather than partner diagnostic intellectual property, providing access to ready-made development expertise.

Another unique characteristic of diagnostic partnering is the number of litigation and settlement agreements relative to the total number of partnering deals.

This report provides details of the latest diagnostics agreements announced in the healthcare sectors.

Understanding the flexibility of a prospective partner’s negotiated deals terms provides critical insight into the negotiation process in terms of what you can expect to achieve during the negotiation of terms. Whilst many smaller companies will be seeking details of the payments clauses, the devil is in the detail in terms of how payments are triggered – contract documents provide this insight where press releases and databases do not.

This report contains a comprehensive listing of all diagnostics partnering deals announced since January 2007, including financial terms where available, including over 2,900 links to online deal records of actual diagnostics partnering deals as disclosed by the deal parties. In addition, where available, records include contract documents as submitted to the Securities Exchange Commission by companies and their partners.

Contract documents provide the answers to numerous questions about a prospective partner’s flexibility on a wide range of important issues, many of which will have a significant impact on each party’s ability to derive value from the deal.

For example, analyzing actual company agreements allows assessment of the following:

- What is actually granted by the agreement to the partner company?
- What exclusivity is granted?
- What are the precise rights granted or optioned?
- What is the payment structure for the deal?
- How are sales and payments audited?
- What is the deal term?
The initial chapters of this report provide an orientation of diagnostics dealmaking and business activities. Chapter 1 provides an introduction to the report, whilst chapter 2 provides an overview of the trends in diagnostics dealmaking since 2007, including details of average headline, upfront, milestone and royalty terms.

Chapter 3 provides a review of the leading diagnostics deals since 2007. Deals are listed by headline value, signed by bigpharma, most active bigpharma, and most active of all biopharma companies. Where the deal has an agreement contract published at the SEC a link provides online access to the contract.

Chapter 4 provides a comprehensive listing of the top 50 bigpharma companies with a brief summary followed by a comprehensive listing of diagnostics deals, as well as contract documents available in the public domain. Where available, each deal title links via Weblink to an online version of the actual contract document, providing easy access to each contract document on demand.

Chapter 5 provides a comprehensive and detailed review of diagnostics partnering deals signed and announced since January 2007, where a contract document is available in the public domain. The chapter is organized by stage of development at signing, deal type (collaborative R&D, co-promotion, licensing etc), and specific therapy focus. Each deal title links via Weblink to an online version of the deal record and where available, the contract document, providing easy access to each contract document on demand.

The report also includes numerous tables and figures that illustrate the trends and activities in diagnostics partnering and dealmaking since 2007.

In conclusion, this report provides everything a prospective dealmaker needs to know about partnering in the research, development and commercialization of diagnostics technologies and products.

If you are seeking deal intelligence on biomarkers, companion diagnostics and personalized medicine, the following report titles may be more targeted to your needs:

- Biomarker Partnering Terms and Agreements
- Companion Diagnostics Partnering Terms and Agreements
- Personalized Medicine Partnering Terms and Agreements
Table of contents

Executive Summary

Chapter 1 – Introduction

Chapter 2 – Trends in diagnostic dealmaking

2.1. Introduction
2.2. Diagnostic partnering over the years
2.3. Most active diagnostic dealmakers
2.4. Bigpharma diagnostic dealmaking activity
2.5. Bigpharma not active in diagnostics
2.6. Diagnostics partnering by deal type
2.7. Diagnostics partnering by stage of development
2.8. Diagnostics partnering by disease type
2.9. Average deal terms for diagnostics partnering
2.9.1 Diagnostics partnering headline values
2.9.2 Diagnostic deal upfront payments
2.9.3 Diagnostics royalty rates
2.10. The anatomy of diagnostic partnering
2.10.1. The anatomy of a diagnostic deal
2.10.1.b. Case study 2: Celera – Siemens Medical Solutions – July 2007
2.11. Litigation and settlement in diagnostics

Chapter 3 – Leading diagnostic deals

3.1. Introduction
3.2. Top diagnostic deals by value
3.3. Top diagnostic deals involving bigpharma
3.4. Leading diagnostics M&A deals by value

Chapter 4 – Bigpharma diagnostic deals

4.1. Introduction
4.2. How to use bigpharma diagnostic partnering deals
4.3. Bigpharma partnering company profiles
   Abbott
   Actavis
   Alcon Labs
   Allergan
   Amgen
   Apotex
   Astellas
   AstraZeneca
   Baxter International
   Bayer
   Biogen Idec
   Boehringer Ingelheim
   Bristol-Myers Squibb
   Celgene
   Cephalon
   Chugai
   CSL
   Daiichi Sankyo
   Dainippon Sumitomo
Chapter 5 – Diagnostic dealmaking directory

5.1. Introduction

5.2. By stage of development
   Discovery
   Pre-clinical
   Phase I
   Phase II
   Phase III
   Regulatory
   Marketed
   Formulation

5.3. By deal type
   Asset purchase
   Assignment
   Bigpharma outlicensing
   Co-development
   Collaborative R&D
   Co-market
   Contract service
   Co-promotion
   CRADA
   Cross-licensing
   Development
   Distribution
   Equity purchase
   Evaluation

Eisai
Eli Lilly
Forest Laboratories
Genzyme
Gilead Sciences
GlaxoSmithKline
Hospira
Johnson & Johnson
Kyowa Hakko Kirin
Lundbeck
Menarini
Merck & Co
Merck KGaA
Mitsubishi Tanabe
Mylan
Novartis
Novo Nordisk
Nycomed Pharma
Otsuka
Pfizer
Roche
Sanofi
Servier
Shionogi
Shire
Stada
Takeda
Teva
UCB
Warner Chilcott
Watson
Grant
Interests
Joint venture
Licensing
Litigation
Loan
Manufacturing
Manufacturing - OEM
Marketing
Material transfer
Option
Promotion
Research
Royalty financing
Settlement
Spin out
Sub-license
Supply
Technology transfer
Termination
Warranty

5.4. By therapy area
Cardiovascular
Central Nervous System
Dental
Dermatology
Gastrointestinal
Genetic disorders
Genitourinary
Hematology
Hormonal
Hospital care
Immunology
Infectives
Inflammatory
Metabolic
Musculoskeletal
Oncology
Ophthalmics
Respiratory
Sensory organs

Chapter 6 – Diagnostic partnering resource center

6.1. Online diagnostic partnering
6.2. Diagnostic partnering events
6.3. Further reading on diagnostic dealmaking

Appendices

Appendix 1 – Deal type definitions
Appendix 2 – Example diagnostics partnering agreement

About CurrentPartnering
Recent titles from CurrentPartnering
Order Form – Reports
Table of figures

- Figure 1: Diagnostic partnering since 2007
- Figure 2: Most active diagnostic dealmakers 2007-2011
- Figure 3: Bigpharma – top 50 – diagnostic deals 2007 to 2011
- Figure 4: Bigpharma diagnostic deal frequency – 2007 to 2011
- Figure 5: Inactive bigpharma in diagnostic dealmaking 2007-2011
- Figure 6: Diagnostics partnering by deal type since 2007
- Figure 7: Diagnostics partnering by stage of development since 2007
- Figure 8: Diagnostics partnering by disease type since 2007
- Figure 9: Diagnostics partnering by oncology target since 2007
- Figure 10: Diagnostic deals with a headline value – by stage of development
- Figure 11: Diagnostic deal headline value distribution – discovery stage, US$million
- Figure 12: Diagnostic deal headline value distribution – discovery stage, US$million - detail
- Figure 13: Diagnostic deal headline value distribution – preclinical stage, US$million
- Figure 14: Diagnostic deal headline value distribution – preclinical stage, US$million
- Figure 15: Diagnostic deals with upfront payment values – by stage of development
- Figure 16: Diagnostic deal upfront payment distribution – discovery stage, US$million
- Figure 17: Diagnostic deal upfront payment distribution – discovery stage, US$million - detail
- Figure 18: Diagnostic deals with milestone payments
- Figure 19: Diagnostic deal milestone payment distribution, US$million
- Figure 20: Diagnostic deals with royalty rates
- Figure 21: Components of the typical diagnostic deal structure
- Figure 22: Settlement licensing agreements since 2003
- Figure 23: Top diagnostic deals by value since 2007
- Figure 24: Top diagnostic deals signed by bigpharma value since 2007
- Figure 25: Top diagnostic M&A deals by value since 2007
- Figure 26: Diagnostic deals by therapy – cardiovascular – 2007 - 2011
- Figure 27: Diagnostic deals by therapy – central nervous system – 2007 - 2011
- Figure 28: Diagnostic deals by therapy – dental – 2007 - 2011
- Figure 29: Diagnostic deals by therapy – dermatology – 2007 - 2011
- Figure 30: Diagnostic deals by therapy – gastrointestinal – 2007 - 2011
- Figure 31: Diagnostic deals by therapy – genetic disorders – 2007 - 2011
- Figure 32: Diagnostic deals by therapy – genitourinary – 2007 - 2011
- Figure 33: Diagnostic deals by therapy – hematology – 2007 - 2011
- Figure 34: Diagnostic deals by therapy – hormonal – 2007 - 2011
- Figure 35: Diagnostic deals by therapy – hospital care – 2007 - 2011
- Figure 36: Diagnostic deals by therapy – immunology – 2007 - 2011
- Figure 37: Diagnostic deals by therapy – infectives – 2007 - 2011
- Figure 38: Diagnostic deals by therapy – inflammatory – 2007 - 2011
- Figure 39: Diagnostic deals by therapy – metabolic – 2007 - 2011
- Figure 40: Diagnostic deals by therapy – musculoskeletal – 2007 - 2011
- Figure 41: Diagnostic deals by therapy – oncology – 2007 - 2011
- Figure 42: Diagnostic deals by therapy – ophthalmics – 2007 - 2011
- Figure 43: Diagnostic deals by therapy – respiratory – 2007 - 2011
- Figure 44: Diagnostic deals by therapy – sensory organs – 2007 - 2011
- Figure 45: Online partnering resources
- Figure 46: Forthcoming partnering events
- Figure 47: Deal type definitions
- Figure 48: Diagnostics partnering agreement between Inhibitex and 3M, February 2007