Defined Health is a leading business development strategy consulting firm. We have been assisting clients in the pharmaceutical, biotech and healthcare investment industries for more than 30 years. Our services, broadly described include:

**Opportunity Assessments**
- potential commercial value of an opportunity
- scientific rationale for an agent vs. other approaches
- future fit of an agent in an evolving standard of care in the next decade
- identification of potential payors or reimbursement issues for a development asset
- minimal and optimal Target Product Profiles required to meet revenue targets
- compelling valuation drivers and potential downsides to support decisions on licensing and M&A

**Therapeutic Area Strategy & Opportunity Identification**
- evaluation of strategic fit of an agent against objectives & goals
- identification of development or marketed compounds to fill a pipeline gap or meet future revenue targets
- identification of potential M&As to expand/augment portfolio
- assessments of other therapeutic areas in which to invest
- assessments of companies to acquire and/or fund
- determination of investment required to continue development

**Licensing & Partnering**
- identification of criteria to identify best partners for an asset (in US, EU, JPN or worldwide)
- identification of ideal target companies for partnering an asset
- determination of key issues that potential partners will evaluate to gauge their interest in an asset or company
- appropriate deal terms and conditions for an asset given historical comparisons & specific situation of our client
- identification & introduction of key contacts at target companies
How Can Defined Health Work With Your Team?

♦ We are flexible with respect to project structure and timelines; all of our projects are done on a single client, custom and confidential basis.

♦ We have broad and deep knowledge across and within therapeutic and disease areas and ample infrastructure in place to start work on a given project quickly – we’re a good resource when time sensitive in-licensing opportunities are in play.

♦ We work either on a fixed cost or a per-diem (hourly) basis depending on client needs.

♦ We scope out projects based on client needs. We can perform a full opportunity assessment with a detailed patient-based 10-year forecast using analogs for ramp up, or conduct a portion of it (market research/ secondary research/ scientific diligence / KOL primary interviews / web based surveys, etc.,) thus complimenting in house expertise and resources on an a la carte basis. Here are some areas where we are often engaged by new product planning/ emerging brand / business development teams:
  • Quick turn around primary market research.
  • Turn-key opportunity assessments including or excluding top-line, peak year or detailed patient based/ script based market forecasts.
  • One off “primer” sessions to bring the team up to speed in a new area.
  • Search and evaluation of strategically-valuable partnering candidates in any therapeutic or disease area of interest; product, technology or company focused; marketed and/or pipeline compounds; with global reach, using flexible screens depending on client needs.
Opportunity Search

Approach & Process
Defined Health is often asked by clients to help define and execute on strategic goals to either establish a new presence or grow an existing presence in one or more therapeutic/specialty areas. This typically involves the identification and qualification of actionable partnering/in-licensing opportunities to strengthen the company’s pipeline across therapeutic/specialty categories of interest.

We fully understand that the identification of strategically-valuable partnering candidates is not easy. As such, we leverage 27 years of experience which gives us an incomparable ability to evaluate and prioritize potential opportunities. Defined Health has helped many companies, including large pharma, specialty pharma and biotech, define and execute on therapeutic area growth strategies.

The following slides outline a typical approach to the identification, prioritization and assessment of potential partnering opportunities for our clients.
Defined Health process below outlines an approach for the identification, prioritization and evaluation of late-stage and marketed compounds in therapeutic/disease areas of interest for potential licensing or acquisition. A detailed explanation of the process follows.

**COMPOUND PROCESS**

- **A1** Develop Screening Criteria & Generate Initial List of Potential Compound Candidates
- **A2** Screen for Compounds that Fit Inclusion Criteria Determined by the client
- **A3** Sort & Prioritize Compound Opportunities within Therapeutic Categories
- **A4** Vet List of Prioritized Compound Opportunities with the client

There will be an interim and final deliverables. Regular interactions with the client will take place throughout the process. Defined Health is committed to working collaboratively and interactively with our clients.

**Deliverable**

Provide Ranking & Preliminary Business Case based on Detailed Analyses for Selected High Priority Compound and Company Opportunities
Once an initial list of compounds is identified, projects typically consist of two-steps with associated deliverables, as described below.

**Starting Point**

**Step 1.**
Initial list of compounds. Compounds in clinical development (phases specified by client) in therapeutic or disease areas of interest and potential availability in geography of interest (e.g., US market). Relative data, information and Defined Health’s commentary and insights are captured in our proprietary search and evaluation tool.

**Actions**

- Confirm phase of development and potential availability in geography of interest.
- Identify as being potentially available for licensing.
- Compile relevant data including indication, moa, development phase, expected launch date, existing partnerships, etc.
- Provide a “quick read” on available data and how this data may translate into position in the relevant treatment algorithm and future marketplace. We also provide a scientific and commercial score for each compound to aid in the prioritization process, as outlined in the following slides.

**Deliverable**

Partnering Landscape

**Step 2.**

**Prioritized list of compounds.** We work collaboratively with our clients, providing additional information and insight, as we finalize the list of potentially interesting compounds.

**Actions**

- Provide greater insight into prioritized compounds with respect to clinical, scientific and commercial potential as outlined in the following slides.

**Deliverable**

Business Case for Prioritized Compounds
Defined Health will rely on secondary research to provide the data to support our analysis. Sources will include, but are not limited to: company pipelines, relevant prescription & pipeline databases, and information gathered from publicly available resources.

DH Knowledgebase: We have extensive experience across all therapeutic sectors in the industry, and will tap our internal database for non-proprietary knowledge of the compound opportunities gained through an extensive network of relationships with BD&L at pharma, specialty and biotech companies.

Defined Health’s consultant and senior consultant staff will supplement its existing understanding of relevant clinical practice with a review of scientific literature, as well as possibly one-to-one discussions with a limited number of KOLs and/or clinicians, as required.

This will focus on covering aspects of current and future therapeutic decision-making, overall need for improved therapeutic offerings and the likely impact of the presumed future competitive landscape.

SELECTED DATA SOURCES
- ADIS R&D Insight pipeline database
- IDdb pipeline database
- EvaluatePharma
- Industry publications (BioCentury, Windhover)
- Scientific literature
- Medical info sites (Medscape, UpToDate)
- Company websites, press releases
- SEC filings
- Analyst reports
- Clinical trial databases
- Defined Health network
The scientific score is intended as a surrogate for clinical development risk for the product. Key attributes are assessed with an eye towards likelihood of success in Phase III clinical trials and/or with FDA approval. For some attributes, specific ranking criteria vary by indication according to unmet needs, current standard of care, competition, etc. in the area.

**Category: Scientific & Clinical**

- **Scientific rationale for MOA**
- **Probability of Success: Development Stage**
- **Probability of Success: Efficacy**
- **Probability of Success: Safety (Tolerability and Adverse Events)**
- **Established Regulatory Pathway**

**Scientific & Clinical Score**

Evaluation of:

- potential for agent to be first or best in class
- fit in clinical environment, i.e. no impact, incremental impact, or transformational
- level of validation of this target
- stage of clinical development & overall likelihood of success
- drug efficacy based on clinical/preclinical data, and how this compares to marketed/competitive products
- safety profile based on clinical/preclinical data and how this compares with marketed/competitive products, e.g. toxicities which may limit efficacy
The commercial score is intended to provide an assessment of the market need and growth potential for the intended indication. Key attributes are assessed with an eye towards the compound’s ability to address unmet need in the condition, impact on the treatment paradigm, and competitive environment challenges.

### Commercial Assessment Score

**Evaluation of:**
- overall size of the target market
- segment of that market in which this agent will be positioned and its potential to capture market share
- potential for an expanded clinical development plan or more rapid path to market
- competitive landscape and analysis of the current market and development pipeline in this area, i.e. whether crowded environment, competitor potential
- ability of client’s franchise strength to offset any negative impact of a crowded marketplace
- contribution of this agent to client’s strategic goals
- alignment in terms of launch window and geography

<table>
<thead>
<tr>
<th>Category: Commercial Assessment</th>
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</thead>
<tbody>
<tr>
<td>✦ Competitive Intensity within Disease Market</td>
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<tr>
<td>✦ Unmet Need in Lead Indication</td>
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<tr>
<td>✦ Growth Potential</td>
</tr>
<tr>
<td>✦ Potential to Expand Beyond Lead Indication</td>
</tr>
<tr>
<td>✦ Strategic Fit</td>
</tr>
</tbody>
</table>
Compounds are then plotted based on commercial and scientific rankings, which provides a snapshot of the pipeline and context for assessing individual opportunities. Promising (and potentially available) agents are selected for more in-depth analysis.

 Agents with low scientific ranking are not subject to commercial analysis.

Target Compounds subjected to in-depth analysis

- Drug A
- Drug B
- Drug C
- Drug D
- Drug E
Detailed evaluations of highly ranked compounds include a summary and analysis of data available to date and potential positioning for the product in the treatment algorithm and market.

Questions Addressed in Deeper Dives of High Priority Compounds:

- What is the **clinical value** proposition of this product within the evolving market?
- Does it offer a unique treatment option?
- Will it add to or displace the current standard of care?
- If successful in clinical development, what benefits will it provide compared to current standards?
- What is the extent and value of the early-stage portfolio?

- What is the **competitive landscape** for this agent?
  - Is it likely to be first-in-class, next generation, or simply another alternative agent?
  - How does it fit into the treatment algorithm?
  - What other companies are developing potential competitors?
  - Do competitive products have similar clinical development paths, or is this product being developed for a unique market niche?

- What is the **strategic value proposition** of this product for the client?
  - Does the product meet the targeted revenue & growth potential goals?
  - Does the product align with the client’s global presence and provide synergistic benefit?
  - Does the company have early-stage pipeline agents that may be attractive for out-licensing, or expansion into specialty areas?
Defined Health Consultant Team

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Members of the Defined Health consulting team have advanced scientific degrees and/or considerable industry experience and are skilled at operating at the interface of the science, clinic and commercial space. We regularly conduct primary research with key opinion leaders as well as generalist and specialist physicians, which continually feeds our already strong grasp of medical management at the ground level.

Our website (www.definedhealth.com) contains multiple presentations on various therapeutic area topics that showcase the way our firm & consultants analyze the important issues that our clients face on a daily basis.
Defined Health is please to present:

www.cancerprogressbyDH.com

www.therapeuticinsight.com