FACILITATING SUCCESSFUL CANCER DRUG DEVELOPMENT

TURNING TRIALS INTO THERAPY
TRIAL ACCELERATION SERVICES:
Physician-Focused Patient Recruitment

TRANSLATING INNOVATION INTO PATIENT CARE
SCIENTIFIC EXCHANGE PROGRAMS:
Tumor and Translational Summits

ONE SOURCE FOR CANCER KNOWLEDGE
STRATEGIC DECISION MAKING:
Innovative Reference Tools and Clinical Insights

CAPABILITIES
The contents of this proposal contain privileged, confidential, and proprietary information to DAVA Oncology LP, d/b/a ONE Oncology (“ONE”). By retaining and reading the contents herein, the reader hereby agrees not to share or transfer to other parties without the written consent of ONE.
Cross-Functional Application

Training & Development • Competitive Intelligence & Business Analysis • Strategic Marketing • Medical Affairs • Clinical Development

A library of one-stop strategic resources and learning tools

Regularly updated and housed in platform-neutral, clickable PDFs

Data incorporation in an intuitive, easy-to-use format

- Publications
- Press Releases
- FDA Opinions & Regulatory Information
- Additional Publicly Available Sources

ONE tumor type ➔ multiple pathways

TUMOR COMPASS

ONE pathway ➔ multiple tumor types

PATHWAY NAVIGATOR
DISEASE OVERVIEW

Disease state information, including clinical, histological, and biological subsets, as well as epidemiology and patient flow

STANDARD OF CARE

Historical perspective of the clinical trials that shaped the current standard of care, including failed trials as lessons learned

PIPELINE BY PATHWAY

Forward-looking analysis of the impact of agents across all stages of development and emerging MOAs, including biomarkers and patient segmentation
ONE pathway ➔ multiple tumor types

PATHWAY NAVIGATOR

PATHWAY ACTIVATION
Pathway overview, prognostic and predictive biomarkers, translational research

TUMOR TYPES
Relevant tumor types are explored; analyses include detailed summaries, available data, ongoing trials, developmental milestones, and impact analysis

AGENT PIPELINE
Key competitors are profiled based on historical analysis, current developmental status, future plans, and market presence

Confidential
A Library of Tools

- Acute Myeloid Leukemia
- Chronic Lymphocytic Leukemia
- Diffuse Large B-Cell Lymphoma
- Follicular Lymphoma
- Mantle Cell Lymphoma
- Marginal Zone Lymphoma
- Waldenstrom Macroglobulinemia
- Multiple Myeloma

Additional Titles Available Upon Request, Including:

- Acute Lymphocytic Leukemia
- T-Cell Lymphoma
- Myeloproliferative Disorders
- Myelodysplastic Disorders
ONE tumor type ➤ multiple pathways

COMPASS Library: Solid Tumors

A Library of Tools

- Bladder Cancer
- Breast Cancer
- Colorectal Cancer
- Glioblastoma
- Hepatocellular Carcinoma
- Non-Small Cell Lung Cancer
- Small Cell Lung Cancer
- Ovarian Cancer
- Pancreatic Cancer
- Prostate Cancer

Additional Titles Available Upon Request, Including:

- Head & Neck Cancer
- Melanoma
- Gastric Cancer
- Renal Cell Carcinoma
Pathway NAVIGATOR Library

ONE pathway ➔ multiple tumor types

Pathway NAVIGATORS

- Checkpoint Inhibition
- AXL Pathway

Coming Soon

- MET Pathway
- PI3K, mTOR & AKT Pathways
- Angiogenesis Pathway
- B-cell Receptor Signaling Pathway
- BRAF & MEK Pathways
Leveraging ONE’s Medical and Scientific Insights to Disseminate Cancer Knowledge

• Full-service content development capabilities leveraging ONE’s scientific expertise and medical oncology insights
• Custom materials for multiple audiences including:
  • Clinical Development Onboarding
  • Commercial Training and Reference Guides
  • Medical Science Liaison Training and Reference Guides
  • Healthcare Provider Education (non-CME)
• In-person training workshops facilitated by medical oncologists experienced in drug development
A Guide to CANCER DRUG DEVELOPMENT

An Interactive Guide

- Housed in a, platform-neutral, clickable PDF format
- Featuring over 125 pages with hyperlinked references
- In-person delivery and introductory training session

Cancer Drug Development

I. Types of Studies
II. Dosing and Scheduling
III. Preclinical Research
IV. Filing an IND
V. Phases: 0-IV
VI. Regulatory Approval
VII. Drug Filing
VIII. Special Designations
IX. Clinical Endpoints
X. Inclusion/Exclusion Criteria
XI. Determining Optimal Patient Numbers
XII. Trial Timelines
XIII. Special Clinical Trial Considerations by World Region
XIV. Understanding the Standard of Care
XV. Sites
XVI. Financial Aspects of Conducting Clinical Trials
CLINICAL AND COMPETITIVE LANDSCAPES

CLINICAL
• Current and future treatment paradigms
• Clinical and molecular patient segmentation
• Epidemiology
• Tumor biology
• Role of biomarkers

COMPETITIVE
• Regulatory strategies
• Development timelines of critical competitors
• Potential impact of novel agents
• New indications on practice patterns

TARGET PRODUCT PROFILE
• Appropriate Tumor Type
• Appropriate mechanism of action
• Minimum barriers to entry based on existing competitive end points
Optimized Drug Development Strategy

- Assess clinical and commercial potential in selected tumor type(s)
  - Explore the unmet needs, the biology, and the rationale behind the drug

- Provide strategic insights and tactical recommendations around a clinical development program designed for drug approval
  - Analyze the existing clinical development plans and assess any gaps
  - Identify key risks in study design and strategies for their mitigation

Optimize clinical potential while limiting competitor impact

- Examine the current clinical landscape and patient flow

Develop clinical insights and recommendations in support of future development opportunities

- Formulate new clinical trials, assess their feasibility, and identify and overcome potential challenges

Validate the life cycle management plan with key internal stakeholders to get views on clinical, regulatory, and marketing aspects
Tailored Strategic Simulation Services

**Generate and consolidate key internal stakeholder input to define strategies and tactics, allowing clients to:**

- Anticipate, react, and respond to competitors’ actions and the evolution of the competitive landscape
- Develop strategies and tactical objections to competitor messaging
- Develop new internal and external planning and product positioning to counter competitive threats
- Validate and vet strategies and tactics with external experts for a comprehensive approach incorporating multiple perspectives
- Shape, capture, and deliver actionable step-by-step plans following the conclusion of each workshop
**Advisory Board Services**

**Global, National, and Regional Capabilities**

- Identification & recruitment of key opinion leaders and thought partners from key academic and community settings
- Complete content and discussion guide development leveraging ONE’s scientific expertise and medical oncology insights
- Moderation by medical oncologists experienced in drug development
- In-house meeting planning, execution, and on-site support including travel, lodging, and all meeting needs
- Executive summary and action plan development by ONE’s Dallas-based team of medical oncologists and oncology-trained research professionals
KEY QUALITATIVE INSIGHTS

In-Depth, MD-Moderated Interviews with Academic and Community Experts

- Key clinical and regulatory events
- Future clinical plans
- Strengths and weaknesses of clinical data
- Key positioning and messaging for clinical data

1. Data research → 2. Discussion guide → 3. MD-Moderated IDIs → 4. Analysis → 5. ONE’s Medical Oncology Insights
ONE Oncology provides comprehensive congress coverage to highlight emerging trends, identify clinical opportunities and track key competitors.

Identify the following for selected tumor types and pathways:

- Educational sessions
- Poster presentations
- Oral presentations
- Plenary sessions
- Question & answer sessions
- Key competitors
- Novel pathways and new agents
- New and evolving biomarkers
- Identified patient subsets
- Impact of presented data on your pipeline
- Impact of presented data on the selected tumor types and pathways
- Insights from ONE medical oncologists and onsite capture
- Clinical trial traffic and congestion
- Development status for competitive agents
- Development and commercial strategies
- Qualitative insights