DUE NORTH®
INNOVATION

Sketch to Launch®

NAVIGATING THE PATH TO COMMERCIALIZATION

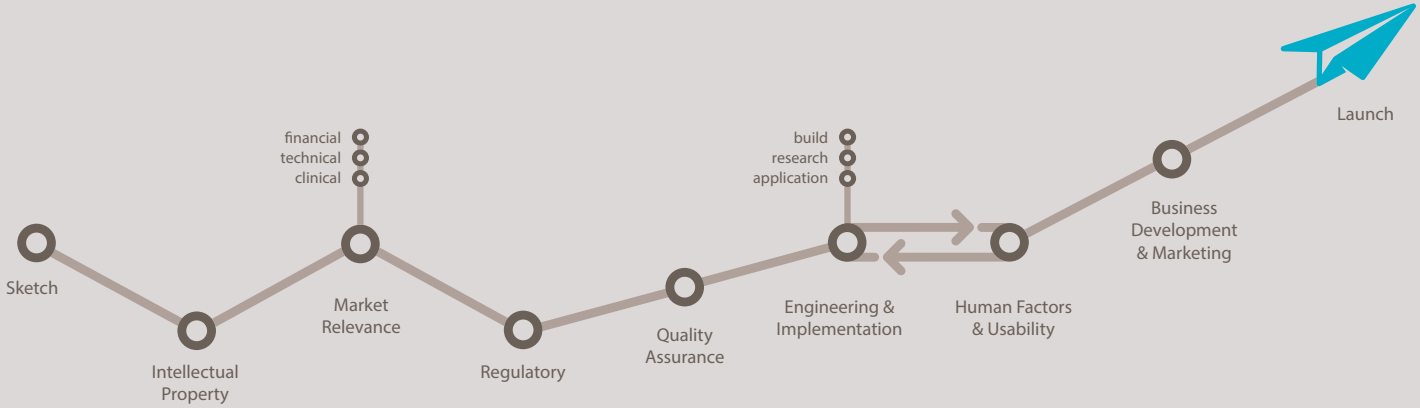
Sketch to Launch®

NAVIGATING THE PATH TO COMMERCIALIZATION

www.**sketch**to**launch**.com

Due North Innovation
Portland, Oregon USA

Contents


Sketch
Intellectual Property
financial
technical
clinical
Market Relevance
Regulatory
Quality Assurance
build
research
application
Engineering & Implementation
Human Factors & Usability
Business Development & Marketing
Launch

From **concept** to **clinical application**

The Sketch to Launch process by Due North is a proven method of advancing medical innovation. Specifically tailored to the unique needs in healthcare, Sketch to Launch is focused on delivering financially viable solutions that improve the quality of patient care.

With its comprehensive end-to-end approach to commercialization, Due North integrates highly specialized, multi-disciplined professionals at every stage of development to ensure the needs of all stakeholders are met in a new product.

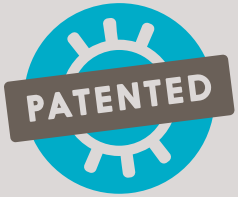
Sketch

Whether it's captured on the back of a napkin or outlined in a formal report, everything starts with an idea. At Due North, we focus on transforming that idea into a plan of action.

Team Building
Specific skill sets and core competencies of team members are matched to the unique development needs of each project and organization.

Concept Development
A collaborative effort among key team members to further analyze, expand and articulate the details surrounding an idea.

Concept Summary
A detailed written and visual summary of the sketch concept that includes an outline and plan of next steps.



Intellectual Property

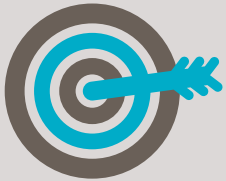
At every stage in the Sketch to Launch process Due North seeks to create, secure and expand the value and protection of innovation through patents, trademarks, copyright and trade secrets.

Landscape Search
A high-level look at published IP with an intent to identify organizations or individuals that are similarly working in the space.

IP Development and Strategy
An evolution or refinement of intellectual property along with a plan to further advance protection.

IP Acquisition
The pursuit and integration of complementary IP to enhance and/or expedite development of the existing innovation.

IP Filing
A thorough encapsulation of a novel innovation including detailed drawings and methods of application in order to successfully secure a patent.



Market Relevance

Due North examines the financial, technical and clinical viability of each idea in parallel to be sure it can impact patient outcomes *and* succeed as a business.

Market Landscape
An overview of the current and future opportunities within a target sector.

Competitive Landscape
A comparative analysis of competitive products with a specific focus on cost, product differentiation and market position.

PRESTLE Analysis
A comprehensive look at seven key factors that may impact a company's marketing and business growth strategies.

SWOT Analysis
An examination of a company's strengths and weaknesses along with opportunities and threats that a company could face.

Clinical

With a thorough and in-depth look at the clinical environment, Due North evaluates the potential of an innovation's ability to improve safety and efficacy while meeting the practical needs of patients and healthcare providers.

Stakeholder Map
A comprehensive visual diagram identifying all individuals and organizations that will be interested and/or impacted by the innovation at hand.

Observational Research
A *"watch and learn"* approach to understanding the clinical environment in which the proposed medical product will be used.

Contextual Research
Use cases, workflow diagrams and/or time-motion studies that document the processes, procedures and problems faced by patients and clinicians.

Customer Profile
Identification of decision makers and their needs in order to ensure that the product will be relevant and appropriately priced.

Technical

Due North physicists and engineers come together to evaluate the technical aspects of a design. Mechanical, electrical, chemical and software requirements are all intensely reviewed for feasibility prior to moving forward in the Sketch to Launch process.

Technical Viability
A practical look at the functionality and feasibility of a concept to answer the fundamental question *“can it work?”*

Technical Landscape
A broad exploration of competitive and complementary technologies in and outside the medical sector.

Technical Development Plan
A phased outline of the cost, timeline and tasks that are required to further technical development.

Market Requirement Specification (MRS)
A detailed written summary that identifies and prioritizes what the product must be capable of doing.

Technical Development Plan
A high-level phased outline of the cost, timeline and tasks expected to be required to further technical development.

Financial

More than simply *"crunching the numbers"*, Due North financial analysts work side-by-side with marketing, technical, clinical and translational strategists to gain a comprehensive understanding of the cost of commercialization.

Financial Viability Model

A comprehensive *"bottom up"* statistical model based on cost and profit margins to determine if a company and/or product can be profitable.

Preliminary COGS

An initial exploration of the *'cost of goods'* or materials, along with the cost of labor and overhead required to produce the product.

Business Model Identification

Identification of the most financially feasible method to sell the future product in the market.

Valuation

Use of a modified Black-Scholes, fair market value (FMV) and investor-based model to estimate company worth.

Regulatory Compliance

The Due North team expertly navigates the regulatory process having successfully cleared numerous devices with the FDA, CE Mark and Health Canada.

Device Classification
Determining a medical device's rating from Class 1, 2 or 3 device (from least to most risk) to create an appropriate regulatory strategy.

Review Criteria
The identification of all documentation necessary to satisfy the clearance requirements of a regulatory agency.

Regulatory Readiness
The documentation and pre-submission communication with regulatory agencies in order to present a comprehensive application.

Regulatory Submission
End-to-end management of the formal submission process including application submission, response to reviewer requests, in-person meetings and all required documentation.

Quality Assurance

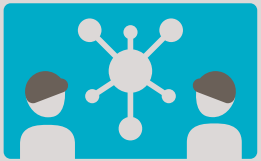
At Due North we are driven by stewardship to reduce risk and ensure reliability as we advance regulatory-compliant products.

Quality Management System (QMS)
Formal system of documentation that captures the design and development process mandatory for regulatory clearance.

QMS Management
The ongoing maintenance of the Design History File (DHF) including documentation control and team member training.

Vendor Qualification
Development of the qualification criteria and formal evaluation of vendors that will supply services or goods to the company.

Quality Audit
Professional support to ensure that a company complies with the processes and procedures of the QMS.



Engineering & Implementation

After exhaustive technical discovery and due diligence, Due North engineers work with the team at large to create an exhaustive plan to efficiently and cost effectively build a product.

Functional Requirement Specification (FRS)
A written summary identifying in detail how the product is intended to function.

Build of Materials (BOM)
A comprehensive list of all parts and materials required to build a product.

Use Cases
An all-inclusive list of tasks or interactions between the user and a system or device to fully understand and document workflow.

Risk Analysis
A formalized, regulatory-compliant process to analyze and evaluate the potential fail points and safety concerns of a product, along with a plan to mitigate and monitor these risks.

Application

Going above and beyond what is required for regulatory clearance, Due North usability and human factors experts utilize several methods to ensure that new products are safe, elegant and easy to use.

Time-Motion Studies
A real-time observation and record of the time it takes to complete each step of a task when using a product or engaging in a process.

Site Visits & Stakeholder Interviews
Watching and talking to patients, clinicians and professionals to identify challenges with current devices or methods to ensure that new technologies will meet market need.

Clinical Studies
Formal, peer-reviewed studies that tests human response to a new product or procedure and identify statistically significant information.

Simulations
Testing in an environment that replicates real-world conditions so that success and failure points of a new product or procedure are determined.

Research

The Due North team digs deeper into the questions that surface during planning sessions to further refine the path forward.

Hardware
A detailed look at the materials and components of a device to determine things like cost, compatibility, integration and efficiency.

Software
The determination of appropriate protocols, configurations, system or institutional restrictions, privileges, privacy and security.

Physics
A focus on things like the mechanics, heat, light, radiation, sound, electricity and magnetism to confirm the principles are sound in a proposed innovation.

Science
An exploration of peer-reviewed studies and published articles to glean knowledge from cutting-edge thought leaders.

Build

The collective and inter-disciplined efforts of the Due North team come to tangible fruition as initial products are built.

Proof of Concept (POC)
A demonstration of all or part of a product, to verify that certain concepts or theories have the potential for real-world application.

Prototyping
A preliminary model of a new device from which future versions will be developed.

Verification and Validation
A T3 cycle where the outcome of three identical consecutive tests confirms that a component or device is functioning as intended 100% of the time.

Pilot Production
An initial, small quantity build of a new product to refine processes for future full-volume manufacturing.

Human Factors & Usability

In addition to meeting safety and efficacy requirements, Due North seeks to understand and optimize how people interact with technology to deliver products that are thoughtfully intuitive and a pleasure to use.

Heuristic Analysis
A structured examination of a product's user interface to determine adherence to recognized usability principles and best practices.

Observational Research
An onlookers perspective and record of how intended users engage with and respond to a newly developed product.

Usability Testing
Hands-on human use of the system in a real-world environment to test key areas of concern to confirm that new features are functioning safely and effectively.

Ergonomics
Intentional focus on the comfort and functional design of a product or process to enhance human well-being and improve overall system performance.

Business Development & Marketing

The Due North team advances awareness and adoption of new technology in the medical sector with a balance of education, promotion and personal connection.

Brand Development
Creation of the name, logo, website and collateral to distinguish a company or product from others.

Market Strategy
The plan to strategically engage, educate and empower customers in a way that establishes a positive connection with the company and product.

PR & Communications
Development of consistent, clear and regulatory-compliant messaging to promote and share information with the public.

Go-to-Market Strategy
A thorough product launch plan with a focus on promotion, sales and distribution.

Launch

Due North directly connects innovators, investors and industry players to execute go-to-market strategies with confidence.

Due Diligence
Creation of a package for investors or licensees to investigate the validity and value of a company or business opportunity surrounding the developed product.

Fundraising
Creation of several tools including the executive summary, company facts sheet and presentation, as well as the formal in-person pitch to investors.

Executive Management
Strategic placement of interim C-level executives to lead the implementation of go-to-market strategies.

Negotiations
Representation on behalf of the innovator to successfully close licensing, funding, merger or acquisition deals.

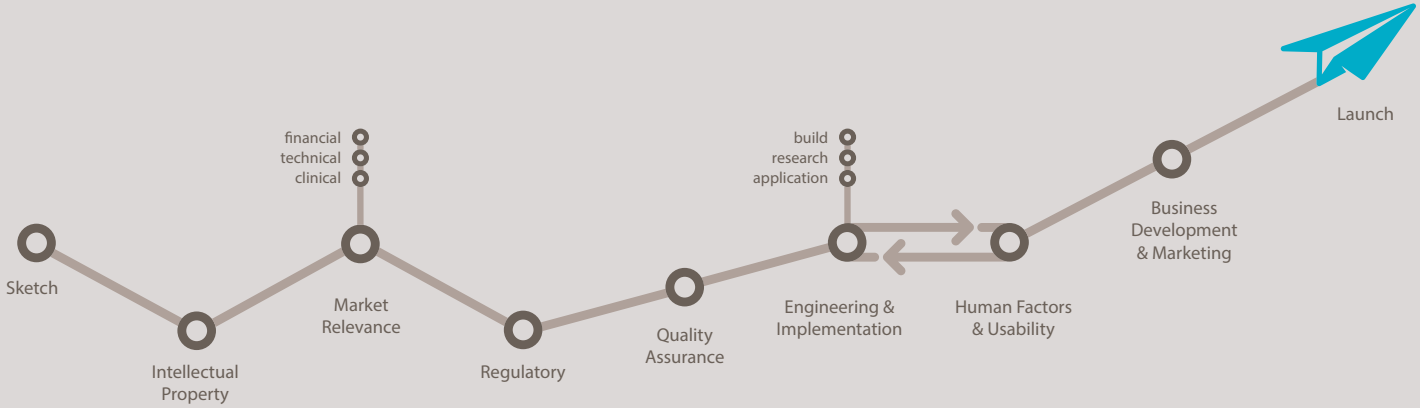
Summary

At Due North we intentionally describe Sketch to Launch as a process, never a formula. Much like rafting a Class 5 rapids or skydiving from 5000 feet, the adventure of commercialization can be a high-risk plight.

As with extreme sports, odds become more favorable when experienced guides are employed to lead the charge. With a level of temperance and expertise that can only be gained with experience, Due North is that seasoned guide.

We navigate the complex terrain of commercialization and innovation every day. With strict adherence to regulatory requirements, we balance a “safety first” approach without ever losing sight of why we embarked on the journey in the first place: because people matter.

Due North transforms technology that improves the lives of patients.


Sketch
Intellectual Property
financial
technical
clinical
Market Relevance
Regulatory
Quality Assurance
build
research
application
Engineering & Implementation
Human Factors & Usability
Business Development & Marketing
Launch

Resources

Food and Drug Administration
The FDA is a US federal agency responsible for monitoring trade and safety standards in food, drugs and medical devices.
www.fda.gov

United States Patent and Trademark Office
The USPTO is a Department of Congress agency that issues patents to inventors and businesses for their inventions and trademark registration for products and intellectual property identification.
www.uspto.gov

European Conformity Marking
CE mark is an indication that a product or device meets all legal requirements stipulated by the EEA, EU and EFTA. This allows for the product to be bought, sold and distributed through the European market.
www.ec.europa.eu

Health Canada
Health Canada is the federal department responsible for the oversight of all health-related industries.
www.hc-sc.gc.ca

ISO 13485:2003
Published by the International Organization for Standardization, ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer needs and regulatory mandates applicable to medical devices and related services.
www.iso.org

Underwriters Laboratories
UL is an American worldwide safety consulting and certification organization that provides safety-related certification, validation, testing, inspection, auditing, advising and training services.
www.ul.com

Canadian Standards Organization
A division of CSA Group, CSA is a not-for-profit organization that develops standards in 57 areas including safety and performance standards for electrical and electronic equipment.
www.csa.ca

Association for the Advancement of Medical Instrumentation
The AAMI standards program consists of over 100 technical committees and working groups that produce standards, recommended practices and technical information reports for medical devices.
www.aami.org

Contact

DUE NORTH®
INNOVATION

411 SW 6th Avenue
Portland, Oregon 97204
USA

Phone: 503.967.3161

www.**sketch**to**launch**.com


DUE NORTH®
INNOVATION