Paragreen Associates

# Business Model Canvas

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Day 1: Complete the Value Proposition and left-hand side of template

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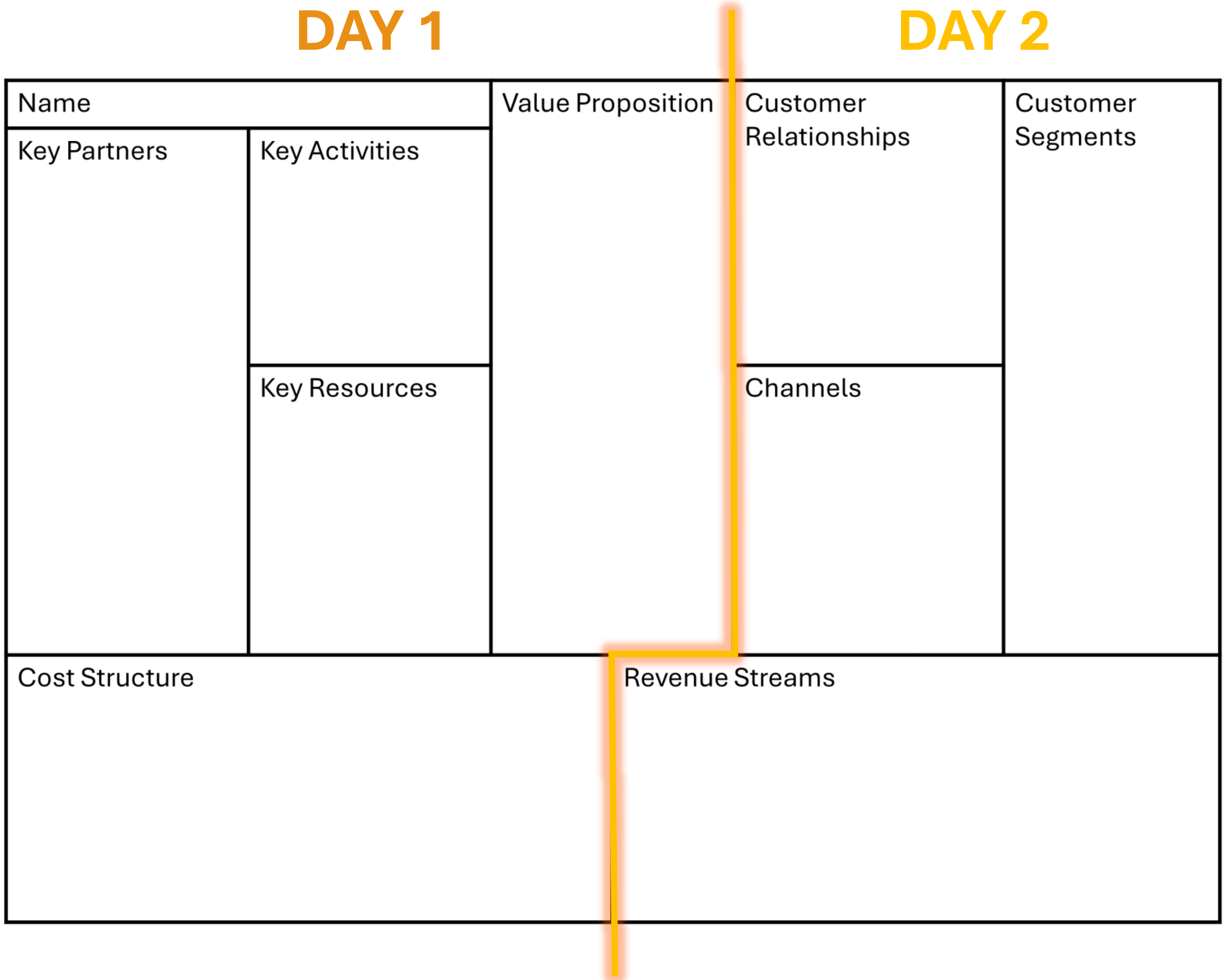
# Beyond the Lab: Introducing the Business Model Canvas for IVD Innovators

- The Business Model Canvas
- Strategic management tool that allows you to visualize and challenge your business model.
- One-page template that breaks down your business into nine fundamental building blocks, providing a holistic view of how your organization creates, delivers, and captures value.

**Think of it as a blueprint for your IVD venture:** It moves beyond just the science, helping you understand the commercial realities.

# The BMC: from invention to business




Credit: Alexander Osterwalder and Strategyzer®

# BMC Template: so what goes where?

DAY 1

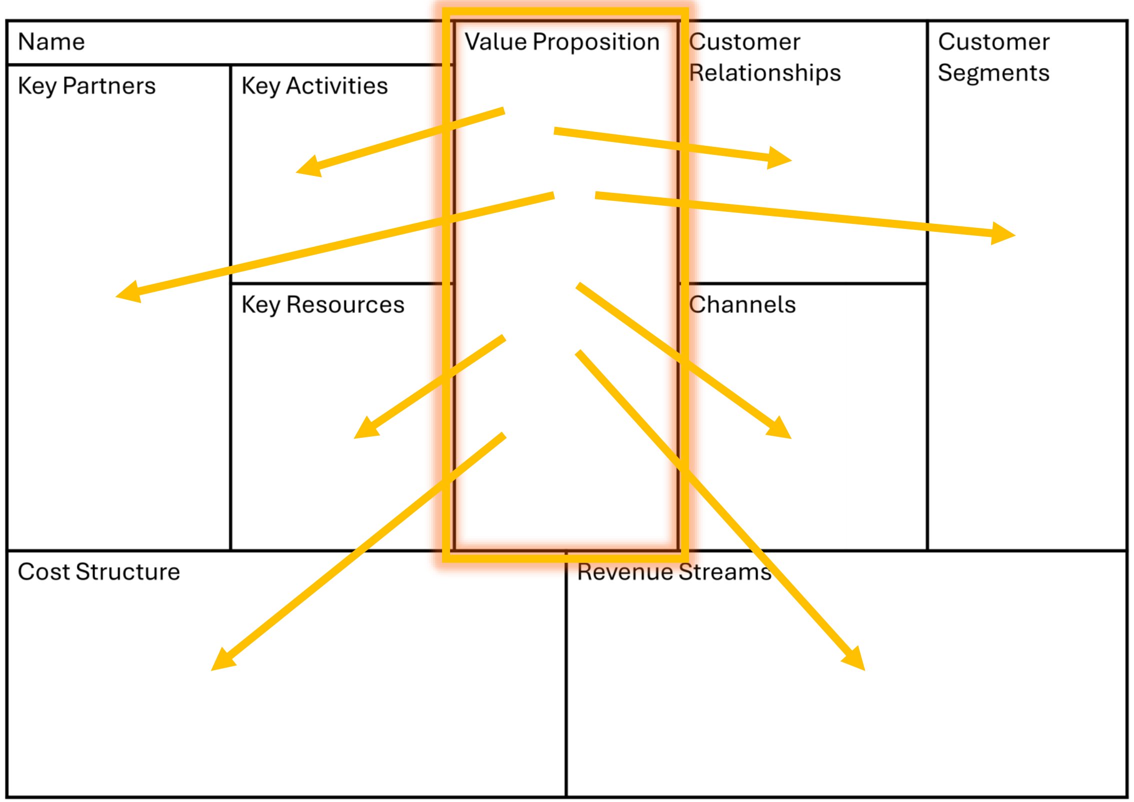
| | |
|---|---|
| Value proposition | What unique value do you deliver to customers? |
| Key resources | What assets are required to offer and deliver your value proposition (e.g., IP, specialized equipment, personnel, capital)? |
| Key activities | What are the most important things your IVD company must do to operate successfully (e.g., R&D, manufacturing, regulatory affairs, marketing)? |
| Key partnership | Who are the external partners you need to succeed (e.g., research collaborators, suppliers, distributors, CROs)? |
| Cost structure | What are the most important costs incurred operating your business model (e.g., R&D, manufacturing, clinical trials, regulatory costs)? |

DAY 2

| | |
|---|---|
| Customer segment | Who are your target customers (e.g., specific clinicians, labs, patients)? |
| Channel | How do you reach and deliver your IVD solution to customers (e.g., direct sales, distributors, online platforms)? |
| Customer relationships | What type of relationship do you establish with each customer segment (e.g., personal assistance, self-service, community)? |
| Revenue streams | How does your IVD business make money (e.g., test sales, subscriptions, licensing)? |

# DAY 1

# Value Proposition: The core of the BMC




**What is a Value Proposition?**

At its heart, a value proposition is a clear, concise statement that explains:

- **What value you deliver.**
- **To whom you deliver it.**
- **How you solve their problem or improve their situation.**
- **Why you are better than the alternatives.**

It's not just about your technology; it's about the *benefit* your technology brings

# Step 1 & 2

**Step 1: Identify Your Target Customer Segment**

- Who exactly are you serving? Be specific!
- **Think:**
  - Is it a specific type of clinician (e.g., oncologists, infectious disease specialists)?
  - A particular hospital department (e.g., pathology lab, emergency room)?
  - A patient group (e.g., those with rare diseases, at-risk populations)?

**Example:**

"Oncologists in community hospitals"

"Clinical lab managers in large academic medical centers."

**Step 2: Understand Their Problem (Pain) or Need (Gain)**

- What challenge does your customer face that your IVD can solve? What are their current frustrations, or what new opportunities can you unlock for them?
- **Think:**
  - Is current diagnosis too slow, expensive, invasive, or inaccurate?
  - Are they missing early detection? Is there a lack of personalized treatment options?

**Example:**

"Current diagnostic methods for early-stage pancreatic cancer are highly invasive and often detect the disease too late for effective intervention."

# Step 3 & 4

**Step 3: Define Your Product/Service**

- Clearly articulate what your IVD solution is.
- **Think:** Is it a
  - Novel biomarker test,
  - Rapid point-of-care device,
  - AI-powered image analysis tool,
  - New sequencing platform?

**Example:** "Our novel liquid biopsy test" or "A portable, automated immunoassay analyzer."

**Step 4: Highlight Key Benefits**

- How does your IVD solve their problem and create tangible value? Focus on the *outcomes* for the customer.
- **Think:**
  - Faster results,
  - Higher accuracy
  - Reduced invasiveness
  - Lower cost,
  - Improved patient outcomes
  - Better treatment selection
  - Increased throughput.

**Example:** "Provides non-invasive, highly sensitive early detection," or "Delivers results within 15 minutes at the patient's bedside."

# Step 5

**Step 5: Articulate Your Differentiators (Why You?)**

- What makes your IVD unique and superior to existing alternatives or competitors?
- **Think:**
  - Patented technology,
  - Superior sensitivity/specificity
  - Ease of use,
  - Lower cost per test
  - Regulatory approval (e.g., FDA breakthrough designation)
  - Unique data insights.

**Example:** "Utilizes a proprietary AI algorithm for unparalleled specificity," or "Is the only CE-IVD marked test for this specific mutation."

# Crafting Your Value Proposition Statement

Template

- **For** [Target Customer Segment]
- **Who** [has this Problem/Need]
- **Our** [Product/Service Name] is a [Category of Product]
- **That** [Key Benefit/Solution]
- **Unlike** [Competitor/Current Alternative]
- **We** [Key Differentiator/USP]

**Example: Early Cancer Detection**

- **For** Oncologists and their patients in high-risk groups
- **Who** face challenges with late-stage diagnosis of pancreatic cancer due to current invasive and insensitive methods
- **Our** "PanDetect" **is a** novel liquid biopsy test
- **That** provides non-invasive, highly sensitive early detection, enabling timely intervention and improving patient survival rates.
- **Unlike** current imaging or biopsy procedures which are invasive and often too late
- **We** utilize a proprietary multi-biomarker panel with 95% specificity, offering a simple blood draw for routine screening.

# Key Partnerships

Who are our Key Partners?

Who are our Key Suppliers?

Which Key Resources are we acquiring from partners?

Which Key Activities do partners perform?

Essential collaborations for IVD market entry:

- Contract Research Organizations (CROs) for clinical trials
- Academic medical centres for clinical validation
- Established diagnostic companies for distribution channels
- Component suppliers (reagents, consumables, instruments)
- Regulatory consultants with IVD expertise
- Key opinion leaders (KOLs) in target therapeutic areas

# Key Activities

- What Key Activities do our Value Propositions require?
- Our Distribution Channels?
- Customer Relationships?
- Revenue streams?

Essential operations for IVD success with timelines:

- Biomarker discovery and validation (12-18 months)
- Assay development and optimization (6-12 months)
- Clinical validation studies (12-24 months)
- Regulatory pathway navigation (FDA 510k, CE-IVD marking)
- Manufacturing process development and scale-up
- Quality management system implementation (ISO 13485)

# Key Resources

- What Key Resources do our Value Propositions require?
- Our Distribution Channels? Customer Relationships?
- Revenue Streams?

Critical assets required for IVD venture success:

- Core IP portfolio (patents, trade secrets, know-how)
- Specialized lab equipment (PCR machines, sequencers, analysers)
- Expert team (PhD scientists, regulatory affairs, clinical)
- Funding runway (£2M-10M for development phases)
- Clinical data and biobank samples
- Regulatory documentation and quality systems

# Cost Structure

- What are the most important costs inherent in our business model?
- Which Key Resources are most expensive?
- Which Key Activities are most expensive?

Critical costs within the IVD business model with realistic estimates:

- R&D personnel (60-70% of early-stage budget)
- Patent filing and IP maintenance (£50k-200k annually)
- Laboratory facilities and equipment (£500k-2M setup)
- Regulatory submission fees (FDA: $300k+, CE: £100k+)
- Clinical trial costs (£1M-5M depending on scope)
- Manufacturing scale-up and quality systems

# DAY 2

# Customer Segments

For whom are we creating value?

Who are our most important customers?

Primary and secondary stakeholders in the IVD ecosystem:

- **Primary users:** Laboratory technicians, pathologists, point-of-care clinicians
- **Decision makers:** Hospital procurement teams, laboratory directors, department heads
- **End beneficiaries:** Patients in acute care, chronic disease management, preventive screening
- **Influencers:** Key opinion leaders, medical societies, guideline committees
- **Regulatory stakeholders:** MHRA, FDA, CE marking bodies, quality assurance teams
- **Payers:** NHS trusts, private insurers, healthcare commissioners

# Channels

- Through which Channels do our Customer Segments want to be reached?
- How are we reaching them now?
- How are our Channels integrated?
- Which ones work best?
- Which ones are most cost-efficient?

Multi-tiered approach to market access

- **Direct sales**: Specialised field application scientists, key account managers
- **Distribution networks**: Regional distributors, GPO partnerships, specialty dealers
- **Digital channels**: E-commerce platforms, webinar series, virtual product demonstrations
- **Professional engagement**: AACC, ECCMID, specialty society meetings
- **Educational outreach**: Clinical evidence publications, peer-reviewed studies, white papers

# Customer Relationships

- What type of relationship does each of our Customer Segments expect us to establish and maintain with them?
- Which ones have we established?
- How are they integrated with the rest of our business model?
- How costly are they?

Building long-term partnerships through:

- **Technical support:** 24/7 helpdesk, field service engineers, remote troubleshooting
- **Training programs:** Certification courses, hands-on workshops, competency assessments
- **Co-development:** Joint clinical studies, beta testing programs, advisory boards
- **Digital platforms:** Customer portals, mobile apps, real-time data analytics
- **Account management:** Dedicated relationship managers, regular business reviews, strategic planning

# Revenue Streams

- For what value are our customers really willing to pay?
- For what do they currently pay?
- How are they currently paying?
- How much does each Revenue Stream contribute to overall revenues?

Diversified income generation models:

- **Equipment sales:** Analyser systems, point-of-care devices, automation solutions
- **Consumables:** Test kits, reagents, quality controls, calibrators (recurring revenue)
- **Service contracts:** Maintenance agreements, software updates, performance guarantees
- **Licensing deals:** Technology licensing, co-marketing agreements, royalty payments
- **Data services:** Analytics platforms, benchmarking services, population health insights

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