Breakthrough Bio

How to Complete This Application

- Complete Section A (Universal), required of every applicant.
- Then complete only the sector section that matches your track: Section B Medical Devices (Medtech) or Section C Pharma (Biotech). You select your track in Question A8.
- For "select one" questions, mark a single box. Where noted, you may select more than one.
- A pitch deck (PDF or PowerPoint) is required.
- Submission deadlines and delivery instructions are provided by the Israel Innovation Authority in the call for proposals.

Section A. Universal Application (All Applicants)

A1. Company name

_____

A2. Company website

_____

A3. Primary contact

Name: _____
Title: _____
Email: _____
Mobile: _____

A4. Founders / executive leadership and relevant background (one sentence each)

Name / Title: _____
LinkedIn URL: _____
Background: _____
Name / Title: _____
LinkedIn URL: _____
Background: _____

A5. City of headquarters

_____

A6. Year founded

_____

A7. Full-time employees (FTEs)

_____

A8. Track (select one; this determines which sector section you complete)

☐ Pharma (Biotech) → Complete Section C
☐ Medical Devices (Medtech) → Complete Section B

A9. In three sentences or fewer: what your company does, who your target customer or stakeholder is, and the problem you solve.

A10. Capital raised to date (USD)

Equity only: $ _____

Total, SAFEs and convertible notes $ _____

Total (Equity, SAFE's and convertible notes): $ _____

Total, incl. debt + grants: $ _____

A11. Most recent funding round (select one)

- ☐ Seed
- ☐ Series A
- ☐ Series B+
- ☐ Other:

A12. Date of last investment raised (must be after Aug 2021) (MM/DD/YYYY):

A13. Primary U.S. objective for this program (select one)

- ☐ U.S. commercialization / market entry
- ☐ Strategic corporate partnership / licensing / co-development
- ☐ Investment / financing
- ☐ Clinical and/or regulatory advancement
- ☐ Other:

A14. Current U.S. presence (select one).

- ☐ None yet
- ☐ U.S.-based advisors, mentors, or informal relationships only
- ☐ Active U.S. conversations underway (customers, partners, or investors)
- ☐ U.S. entity or office established
- ☐ U.S.-based staff or leadership in place

A15. Select up to three R&D or development capabilities you most want to build or strengthen through this program.

- ☐ Preclinical or clinical development
- ☐ Regulatory strategy and pathway execution
- ☐ Clinical trial or study design
- ☐ CMC, manufacturing, or scale-up
- ☐ Data and evidence generation
- ☐ Product development or engineering
- ☐ Intellectual property strategy
- ☐ R&D talent and team building
- ☐ Other:

A16. In one or two sentences: what would make this program a success for you within 12 months of completion? Name the single most important outcome you are seeking.

A17. Pitch deck: upload to application portal as PDF or PowerPoint.

Recommended contents: problem, solution, market opportunity, product/technology and stage, business model, go-to-market, competitive landscape, traction/milestones, team, and financials.

A18. Mentorship: select up to three areas where you could most benefit from support

- ☐ Finance & Investment
- ☐ Go-to-Market / Sales
- ☐ Legal or Regulatory
- ☐ Manufacturing / Distribution
- ☐ Marketing / Branding
- ☐ User Research & Product Development
- ☐ Leadership & Teams
- ☐ Clinical / Scientific Strategy

A19. Travel commitment (required). The program includes three in-person U.S. moments in 2027: Boston (January), San Diego (March), and Philadelphia (June). Please confirm that a founder or executive team member will attend all three events.

- ☐ Yes
- ☐ No (please explain):

A20. Strategic partners, clinical collaborators, or research-institution partnerships (list up to three):

Section B. Medical Devices (Medtech) Questions

Complete this section only if you selected Medical Devices (Medtech) in A8.

B1. Device category (select up to two)

- ☐ Therapeutic / interventional device
- ☐ Surgical tool / robotics
- ☐ Implantable device
- ☐ Diagnostic (in vitro / lab)
- ☐ Imaging
- ☐ Wearable / remote monitoring
- ☐ Connected or software-enabled device
- ☐ Other: _____

B2. Expected FDA device pathway / risk class (select one)

- ☐ Not sure yet
- ☐ Class I / 510(k)-exempt (low risk)
- ☐ Class II: 510(k) (moderate risk)
- ☐ De Novo anticipated
- ☐ Class III: PMA (high risk / life-sustaining)
- ☐ Non-US pathway only to date (e.g., EU MDR / CE, other):

B3. Current product stage (select one)

- ☐ Prototype validated in lab
- ☐ Pilot-ready or in field testing
- ☐ Early commercial / first revenue
- ☐ Scaling commercial

B4. Current sales stage (select one)

- ☐ Pre-commercial (no regulatory clearance or revenue yet)
- ☐ Limited market release / pilot (first clinical sites or paying customers; less than $250K in revenue)
- ☐ Early commercial ($250K to $2M in cumulative revenue; active sales underway)
- ☐ Growth stage ($2M to $10M in cumulative revenue; expanding customer base)
- ☐ Scaling commercial ($10M+ in cumulative revenue)

B5. Highest level of clinical or real-world evidence to date (select one)

- ☐ None yet
- ☐ Bench / lab data only
- ☐ Animal / preclinical data
- ☐ Human pilot or feasibility study in progress
- ☐ Published clinical study

B6. Reimbursement / payment pathway (select all that apply)

- ☐ Unknown / to be determined
- ☐ Direct B2B sales to providers / health systems
- ☐ Payer coverage / reimbursement
- ☐ Existing billing code (CPT / HCPCS / DRG)
- ☐ New billing code planned / in progress
- ☐ Cash-pay / direct-to-consumer
- ☐ Value-based / risk-based contract

B7. Intellectual property and regulatory status (select all that apply)

- ☐ No IP filings or regulatory submissions to date
- ☐ Patent filed (provisional, PCT, or national phase)
- ☐ Patent granted (at least one jurisdiction)
- ☐ Freedom-to-operate (FTO) analysis completed
- ☐ FDA clearance or approval obtained (510(k), De Novo, or PMA)
- ☐ Non-US regulatory clearance obtained (e.g., CE Mark, AMAR/ILDC, PMDA, TGA)
- ☐ Exclusive license agreement in place

B8. In 100 words or fewer: your U.S. commercialization thesis (how you will win with providers, payers, distribution, or strategic partners), and the single biggest barrier you anticipate.

Section C. Pharma (Biotech) Questions

Complete this section only if you selected Pharma (Biotech) in A8.

C1. Therapeutic modality (select up to two)

- ☐ Small molecule
- ☐ Biologic
- ☐ Cell therapy
- ☐ Gene therapy
- ☐ Other:

C2. Lead program stage (select one)

- ☐ Discovery / target identification
- ☐ Lead candidate identified (in vitro data)
- ☐ Preclinical in vivo (efficacy / tox) underway or complete
- ☐ IND-enabling studies
- ☐ Clinical (Phase 1 or later)

C3. Partnering and commercial stage (select one)

- ☐ Pre-partnership (no licensing, co-development, or commercial agreements in place)
- ☐ Early partnering (research collaboration or grant-funded partnership in place)
- ☐ Strategic deal signed (licensing, co-development, or option agreement executed)
- ☐ Multiple deals or significant partnership revenue
- ☐ Clinical-stage commercialization (a partnered or proprietary program in registrational/late-stage trials, or a commercialization/launch agreement already in place
- ☐ Marketed Product (one of more approved products generating commercial or royalty revenue)

C4. Lead indication / therapeutic area (and up to two additional indications, if any)

Lead indication:

Additional:

C5. Strongest evidence generated to date (select one)

- ☐ In silico / target validation only
- ☐ In vitro proof of concept
- ☐ Animal / preclinical efficacy demonstrated
- ☐ Preclinical safety / tox package
- ☐ Human clinical data

C6. Regulatory pathway (select one)

- ☐ Unknown / not sure yet
- ☐ FDA (US) pathway identified
- ☐ EMA or other ex-US pathway identified
- ☐ Orphan / expedited pathway anticipated (e.g., Fast Track, Breakthrough Therapy, RMAT)

C7. Manufacturing / CMC readiness (select one)

- ☐ No CMC or manufacturing work initiated yet
- ☐ Formulation / process development underway (pre-GMP)
- ☐ CDMO or manufacturing partner identified but not yet engaged
- ☐ CDMO / manufacturing partner engaged; development-stage agreement in place
- ☐ GMP batch produced (clinical or commercial grade)

C8. Intellectual property status (select all that apply)

- ☐ No filings to date
- ☐ Provisional patent application filed
- ☐ PCT or national-phase patent application filed
- ☐ Patent granted (at least one jurisdiction)
- ☐ Freedom-to-operate (FTO) analysis completed
- ☐ Trade secret / know-how strategy (no patent filings planned)

C9. In 100 words or fewer: your U.S. market thesis (pharma partnering, licensing / co-development, clinical, regulatory, or investment focus), and the single biggest barrier you anticipate.

Declaration and Signature

By typing my full name below, I certify that I am authorized to submit this application on behalf of the applicant company, and that all information provided in this application is true, accurate, and complete to the best of my knowledge. I understand that any false, misleading, or incomplete information may result in disqualification from the Program.

Full name (typed signature): _____
Title: _____
Company: _____
Date: _____