HELIX OPTICS · MARKET-ENTRY ASSESSMENT · PIPELINE RUN REPORT

# Four markets in, one recommendation out

```
run 31 Aug 2026 16:09 UTC  ai mode: cruise  llm calls: 0 · cost €0.00  runtime 1.73s
eval 28/28  extraction: 74 det / 0 ai / 0 manual / 0 unresolved
```

**Recommendation: enter the Netherlands first.** Break-even in Year 3, cash trough €1.30M, five-year end cash €9.63M. The only market of the four that does not exhaust the €4.0M runway. Each 100 patients triaged saves the Dutch system €7,750.

## 1 · Ingestion: every file, its fate

✓ **1_Company_Briefing.pdf**
PDF · 354ms · sha 68aeddf8

✓ **2_Market_Landscape.pdf**
PDF · 583ms · sha 3458005e

✓ **4_Funding_Call.pdf**
PDF · 105ms · sha c93d4464

✓ **6_Competitor_Brief_OncoStream.pdf**
PDF · 141ms · sha acb9e7b1

✓ **3a_Facilities_Portugal.csv**
CSV · 4ms · sha d4344ba8

✓ **5a_Screening_Report_Portugal.pdf**
PDF · 62ms · sha 55f5291e

✓ **3b_Facilities_Germany.xlsx**
XLSX · 111ms · sha fdf06f71

✓ **5b_Screening_Report_Germany.pdf**
PDF · 87ms · sha 3079b24e

✓ **3c_Facilities_Netherlands.html**
HTML · 93ms · sha 8917d4ac

✓ **5c_Screening_Report_Netherlands.html**
HTML · 21ms · sha fde335a6

✓ **3d_Facilities_Poland.csv**
CSV · 3ms · sha 48ced7ba

✓ **5d_Screening_Report_Poland.xlsx**
XLSX · 5ms · sha 38e4fa80

✓ **3e_Master_Registry.csv**
CSV · 2ms · sha 3ade7285

## 2–3 · Canonical dataset (method-badged)

| PARAMETER | PORTUGAL | GERMANY | NETHERLANDS | POLAND |
|---|---|---|---|---|
| **Eligible population 50–74** | 3,050,000 DET · P1 | 26,400,000 DET · P1 | 4,950,000 DET · P1 | 11,200,000 DET · P1 |
| **Participation** | 43.0% DET · P1 | 22.0% DET · P1 | 71.0% DET · P1 | 17.0% DET · P1 |
| **FIT positivity** | 6.2% DET · P1 | 6.0% DET · P1 | 9.1% DET · P1 | 6.5% DET · P1 |
| **Annual screened** | 655,750 DERIVED | 2,904,000 DERIVED | 1,757,250 DERIVED | 952,000 DERIVED |
| **Addressable FIT+ / yr** | 40,656 DERIVED | 174,240 DERIVED | 159,910 DERIVED | 61,880 DERIVED |
| **Price per test** | €155 DET · P1 | €235 DET · P1 | €215 DET · P1 | €115 DET · P2 |
| **Months to reimbursement** | 12 DET · P1 | 24 DET · P2 | 12 DET · P1 | 12 DET · P3 |
| **Colonoscopy tariff** | €400 DET · P1 | €700 DET · P1 | €650 DET · P1 | €300 DET · P1 |
| **One-time entry cost** | €120,000 DET · table | €450,000 DET · table | €200,000 DET · table | €150,000 DET · table |
| **In-market cost / yr** | €250,000 DET · table | €600,000 DET · table | €350,000 DET · table | €300,000 DET · table |

A star on a pattern id (`P1*`) means the value came from a document whose text was hand-corrected in the file editor; the file on disk is untouched and the correction is listed in `edits.yaml`.
Precedence: national screening report → landscape table → other. Full provenance per value in `markets.csv`; manual corrections belong in `overrides.yaml`, never in outputs.

## 4 · Facilities: one row per real unit

**3,236**
raw register records

**228**
real facilities

**126**
monthly rows ×12

**6**
corrupted rows handled

**208**
type conflicts (majority vote)

**226**
capacity conflicts (median + range)

| UID | FACILITY | COUNTRY | TYPE (VOTES) | CAPACITY/ YR [RANGE] | # RECORDS |
|---|---|---|---|---|---|
| HLX-GE-001 | Charite Universitaetsmedizin · Unit 1 | Germany | Endoscopy (Endoscopy:13/ Pathology:4) | 3800 [1500–5200] | 17 |
| HLX-GE-002 | Charite Universitaetsmedizin · Unit 2 | Germany | Endoscopy (Endoscopy:18/ Pathology:4) | 2900 [850–4100] | 22 |
| HLX-GE-003 | Charite Universitaetsmedizin · Unit 3 | Germany | Endoscopy (Endoscopy:28/ Pathology:9) | 2900 [850–5200] | 37 |
| HLX-GE-004 | Charite Universitaetsmedizin · Unit 4 | Germany | Endoscopy (Endoscopy:18/ Pathology:5) | 3500 [850–5200] | 23 |
| HLX-GE-005 | | Germany | | 2900 [850–4100] | 13 |

| UID | FACILITY | COUNTRY | TYPE (VOTES) | CAPACITY/ YR [RANGE] | # RECORDS |
|---|---|---|---|---|---|
| | Charite Universitaetsmedizin · Unit 5 | | Endoscopy (Endoscopy:10/ Pathology:3) | | |
| HLX-GE-006 | Charite Universitaetsmedizin · Unit 6 | Germany | Endoscopy (Endoscopy:18/ Pathology:2) | 3204 [852–5200] | 20 |

**The rule:** repair unambiguous column-shifts, else exclude (6 handled) → normalise (diacritics; Germany's 126 monthly capacities ×12; ENDO/PATH/'Endoscopy Unit' → one label) → entity = (country, canonical institution, unit n°); register ids are untrusted → master-registry names mapped via a curated, fuzzy-seeded alias table; national register is authoritative → type by majority vote, capacity as median of non-null values with min–max spread reported. Disagreements are surfaced, never silently resolved.

## 5 · Source agreement

| SCOPE | PARAMETER | VERDICT | SOURCES |
|---|---|---|---|
| Germany | colonoscopy_tariff | AGREE | **screening_report**: 700 · **market_landscape**: 700 |
| Germany | eligible_population | AGREE | **screening_report**: 26400000 · **market_landscape**: 26400000 |
| Germany | fit_positivity | AGREE | **screening_report**: 0.06 · **market_landscape**: 0.06 |
| Germany | participation | AGREE | **screening_report**: 0.22 · **market_landscape**: 0.22 |
| Germany | price_per_test | AGREE | **screening_report**: 235 · **market_landscape**: 235 |
| Germany | time_to_reimbursement_months | AGREE | **screening_report**: 24 · **market_landscape**: 24 |
| Netherlands | colonoscopy_tariff | AGREE | **screening_report**: 650 · **market_landscape**: 650 |
| Netherlands | eligible_population | AGREE | **screening_report**: 4950000 · **market_landscape**: 4950000 |
| Netherlands | fit_positivity | AGREE | **screening_report**: 0.091 · **market_landscape**: 0.091 |
| Netherlands | participation | AGREE | **screening_report**: 0.71 · **market_landscape**: 0.71 |
| Netherlands | price_per_test | AGREE | **screening_report**: 215 · **market_landscape**: 215 |
| Netherlands | time_to_reimbursement_months | AGREE | **screening_report**: 12 · **market_landscape**: 12 |
| Poland | colonoscopy_tariff | AGREE | **screening_report**: 300 · **market_landscape**: 300 |
| Poland | eligible_population | AGREE | **screening_report**: 11200000 · **market_landscape**: 11200000 |
| Poland | fit_positivity | AGREE | **screening_report**: 0.065 · **market_landscape**: 0.065 |
| Poland | participation | AGREE | **screening_report**: 0.17 · **market_landscape**: 0.17 |
| Poland | price_per_test | AGREE | **screening_report**: 115 · **market_landscape**: 115 |

| SCOPE | PARAMETER | VERDICT | SOURCES |
|---|---|---|---|
| Poland | time_to_reimbursement_months | AGREE | **screening_report**: 12 · **market_landscape**: 12 |
| Portugal | colonoscopy_tariff | AGREE | **screening_report**: 400 · **market_landscape**: 400 |
| Portugal | eligible_population | AGREE | **screening_report**: 3050000 · **market_landscape**: 3050000 |
| Portugal | fit_positivity | AGREE | **screening_report**: 0.062 · **market_landscape**: 0.062 |
| Portugal | participation | AGREE | **screening_report**: 0.43 · **market_landscape**: 0.43 |
| Portugal | price_per_test | AGREE | **screening_report**: 155 · **market_landscape**: 155 |
| Portugal | time_to_reimbursement_months | AGREE | **screening_report**: 12 · **market_landscape**: 12 |

## 6 · Validation findings

PASS **CHK-01** Landscape vs national report agreement

24 multi-source parameters compared; 0 disagreement(s)

FAIL **CHK-02** Competitor volume vs addressable market handled

OncoStream claims 300,000 tests/yr but Germany's entire organised addressable volume is 174,240/yr (1.7x the whole market). Company-reported figure REJECTED for modelling; the independent 35-40% share estimate (~61-70k tests/yr) is retained instead.

handled: the company-reported figure is excluded from the model; the independent share estimate is used

*A vendor cannot process more triage tests than the entire organised addressable volume. Company-reported figures must be checked against primary screening statistics.*

WARN **CHK-03** Competitor claim vs its own analyst share estimate handled

fails for Germany

handled: same figure as CHK-02, excluded from the model

*The 300k claim should also be consistent with the 35-40% independent share estimate quoted in the same brief.*

PASS **CHK-04** Rates are valid fractions

0 out-of-range value(s)

PASS **CHK-05** Deferral rate consistent with sensitivity/specificity

holds for company

PASS **CHK-06** Facility capacity plausibility

126 monthly rows annualised x12; 0 endoscopy unit(s) without resolvable capacity

PASS **CHK-07** Screened volume arithmetic

holds for Portugal, Germany, Netherlands, Poland

INFO **CHK-08** Colonoscopy demand vs national endoscopy capacity

Portugal: 40,656 referrals vs 165,425 register capacity (25% utilisation) | Germany: 174,240 referrals vs 156,433 register capacity (111% utilisation) | Netherlands: 159,910 referrals vs 155,800 register capacity (103% utilisation) | Poland: 61,880 referrals vs 145,125 register capacity (43% utilisation)

*FIT-positive referrals compared with deduplicated national endoscopy capacity - a utilisation, not an error, check.*

PASS **CHK-09** Absolute values inside plausible ranges

0 out-of-range value(s)

## Evidence gaps, and the research workflow (deliberately off)

**GAP-01** · Germany · opportunistic testing volume

Research this

Explicitly not centrally reported; excluded from the base case per the national report. *Upside only - could enlarge German addressable volume.*

Research plan (what the sourcing workflow would run)

- Query: KBV/G-BA opportunistic FIT volume statistics
- Source type: statutory insurance billing data (EBM codes)
- Fills: Germany.opportunistic_volume (quarantined until human-approved)

**GAP-02** · all · competitor list price

Research this

Competitor brief says 'broadly similar list price' - no number anywhere in the pack. *Pricing pressure scenario in NL/PT/PL cannot be quantified.*

Research plan (what the sourcing workflow would run)

- Query: OncoStream tender records, national procurement portals
- Source type: public tender award notices
- Fills: competitor.list_price per market (quarantined until human-approved)

**GAP-03** · company · IVDR certification timeline

Research this

Single source (company briefing, 'expected within about a year'); no corroboration. *A slip would not block CE-marked sales but matters for tenders.*

Research plan (what the sourcing workflow would run)

- Query: notified-body queue times for IVDR class C assays
- Source type: MedTech Europe / notified body reports
- Fills: company.ivdr_expected_months (quarantined until human-approved)

**GAP-04** · all · penetration benchmark

Research this

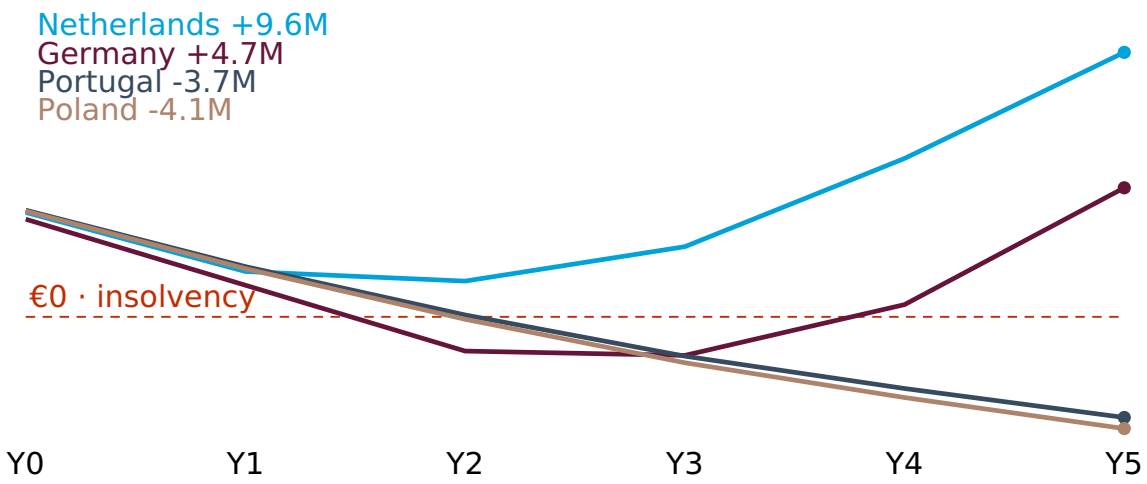
Ramp rests on ONE comparable pilot ('one fifth of eligible volume within three years'). *The single most sensitive model input; the ±50% ramp scenario brackets it.*

Research plan (what the sourcing workflow would run)

- Query: published uptake curves for triage assays post-reimbursement
- Source type: peer-reviewed screening-programme evaluations
- Fills: company.penetration_benchmark corroboration (quarantined until human-approved)

The pack is treated as the **closed source of truth**: no external data was mixed in. In production the Research action launches a sourcing workflow whose finds land in quarantine - parsed and previewed, entering the dataset only after human approval (provenance *EXTERNAL/approved-by*).

## 7 · Conclusion: the five-year engine, all four markets




| # | MARKET | ADDRESSABLE FIT+/YR | PRICE | BREAK-EVEN | CASH TROUGH | END CASH Y5 | |
|---|---|---|---|---|---|---|---|
| 1 | **Netherlands** | 159,910 | €215 | Year 3 | €1.30M | €9.63M | survives |
| 2 | **Germany** | 174,240 | €235 | Year 4 | €-1.41M | €4.70M | insolvent |
| 3 | **Portugal** | 40,656 | €155 | - | €-3.67M | €-3.67M | insolvent |
| 4 | **Poland** | 61,880 | €115 | - | €-4.07M | €-4.07M | insolvent |

### Netherlands, year by year

| YEAR | RAMP | TESTS | REVENUE | COGS/ TEST | GROSS MARGIN | EBITDA | CASH |
|---|---|---|---|---|---|---|---|
| Y1 | 0% | 0 | €0 | €58 | €0 | €-2,150,000 | €1,650,000 |
| Y2 | 7% | 11,194 | €2,406,646 | €54 | €1,796,589 | €-353,411 | €1,296,589 |
| Y3 | 13% | 20,788 | €4,469,484 | €51 | €3,409,281 | **€1,259,281** | €2,555,870 |
| Y4 | 20% | 31,982 | €6,876,130 | €48 | €5,356,985 | **€3,206,985** | €5,762,855 |
| Y5 | 22% | 35,180 | €7,563,743 | €44 | €6,015,814 | **€3,865,814** | €9,628,669 |

Same engine as the Excel model (assumptions editable there); ramp anchored on the pack's benchmark : a comparable assay reached ~20% of eligible FIT-positive volume within 3 years of reimbursement. Germany's pre-reimbursement revenue is held at zero per its national report; its 24-month pathway consumes the runway before first revenue; the largest market is unaffordable now, not unattractive forever.