HELIX OPTICS · MARKET-ENTRY ASSESSMENT · PIPELINE RUN REPORT

Four markets in, one recommendation out

```
run 31 Aug 2026 10:36 UTC  ai mode: auto  llm calls: 0 · cost €0.00  runtime 1.58s

eval 28/28  extraction: 74 det / 0 ai / 1 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

✓ **2_Market_Landscape.pdf**
PDF · 579ms · sha 3458005e

✓ **4_Funding_Call.pdf**
PDF · 101ms · sha c93d4464

✓ **6_Competitor_Brief_OncoStream.pdf**
PDF · 95ms · sha acb9e7b1

✓ **1_Company_Briefing.pdf**
PDF · 346ms · sha 68aeddf8

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

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

✓ **3b_Facilities_Germany.xlsx**
XLSX · 89ms · sha fdf06f71

✓ **5b_Screening_Report_Germany.pdf**
PDF · 78ms · sha 3079b24e

✓ **3c_Facilities_Netherlands.html**
HTML · 90ms · 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	79,999 MANUAL	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

FAIL **CHK-07** Screened volume arithmetic open · needs a human

fails for Portugal

needs a human: correct the source value in overrides.yaml (with a reason) or re-run in Overdrive so the model can re-read it

Addressable = eligible x participation / 2 (biennial) x positivity, recomputed from components.

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

Portugal: 79,999 referrals vs 165,425 register capacity (48% 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

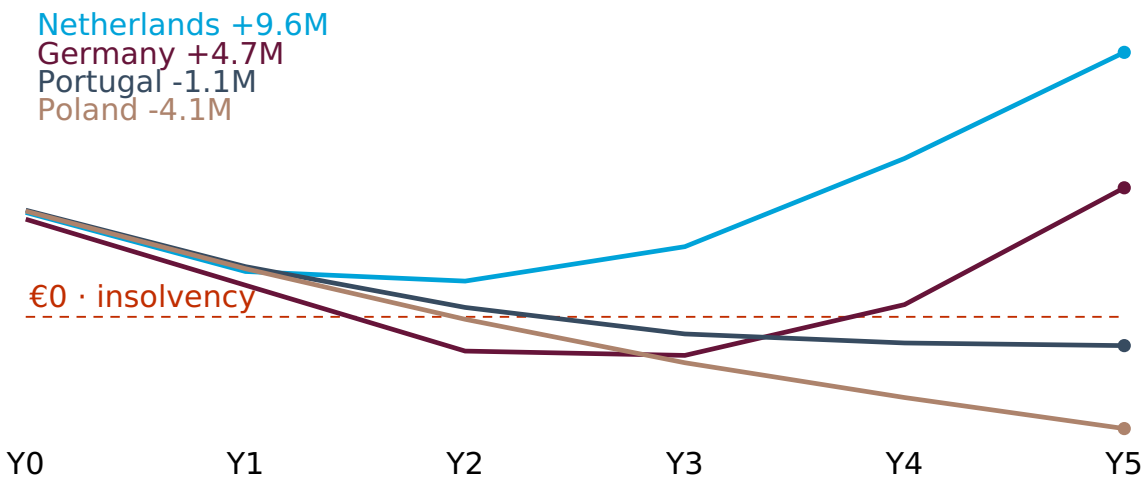
Ramp rests on ONE comparable pilot ('one fifth of eligible volume within three years'). *The single most sensitive model input; the ±50% ramp scenario brackets it.*

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**	79,999	€155	-	€-1.05M	€-1.05M	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.