



Driving Global Change: Turning Technology into Healthcare Success Stories

Tom Hueting, Evidencio



EVIDENCIO
MEDICAL DECISION SUPPORT

Transforming

AI Algorithms

into Certified Medical Devices



The idea of Evidencio

The Breast 22 (2013) 773–779

Contents lists available at SciVerse ScienceDirect

The Breast

journal homepage: www.elsevier.com/brst



ELSEVIER



Original article

A validated web-based nomogram for predicting positive surgical margins following breast-conserving surgery as a preoperative tool for clinical decision-making



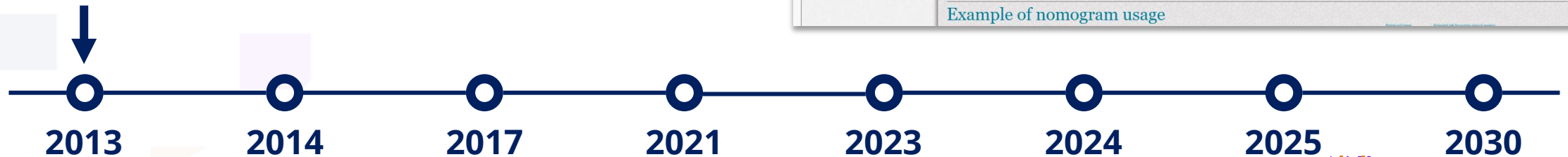
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Instructions

The basic model requests the input of information obtained from preoperative imaging and clinical examination. If a core needle biopsy is performed and preoperative pathological information is available, the expanded model should be used instead.

Although it is not required to enter all variables, entering as many variables as possible will result in a more patient-tailored risk estimation.

For more detailed information regarding these models please check the info page.

Patient and tumor characteristics

Basic Expanded

- Yes
- Absent
- Negative
- T₁
- 0-25%
- Palpable
- No

Calculate Clear Print

Estimated risk for positive surgical margins:

Predicted probability: 8%

Interpretation:

If there would be a group of 100 patients with the same characteristics as this individual patient, 8 patients are expected to have positive surgical margins after breast-conserving therapy.

Based on an a priori risk of approximately 20% in the general population, this particular patient has a **low risk** of positive surgical margins.

Due to the fact that the model is only an approximation of the true situation, the estimated risk may deviate from the actual risk for positive surgical margins.

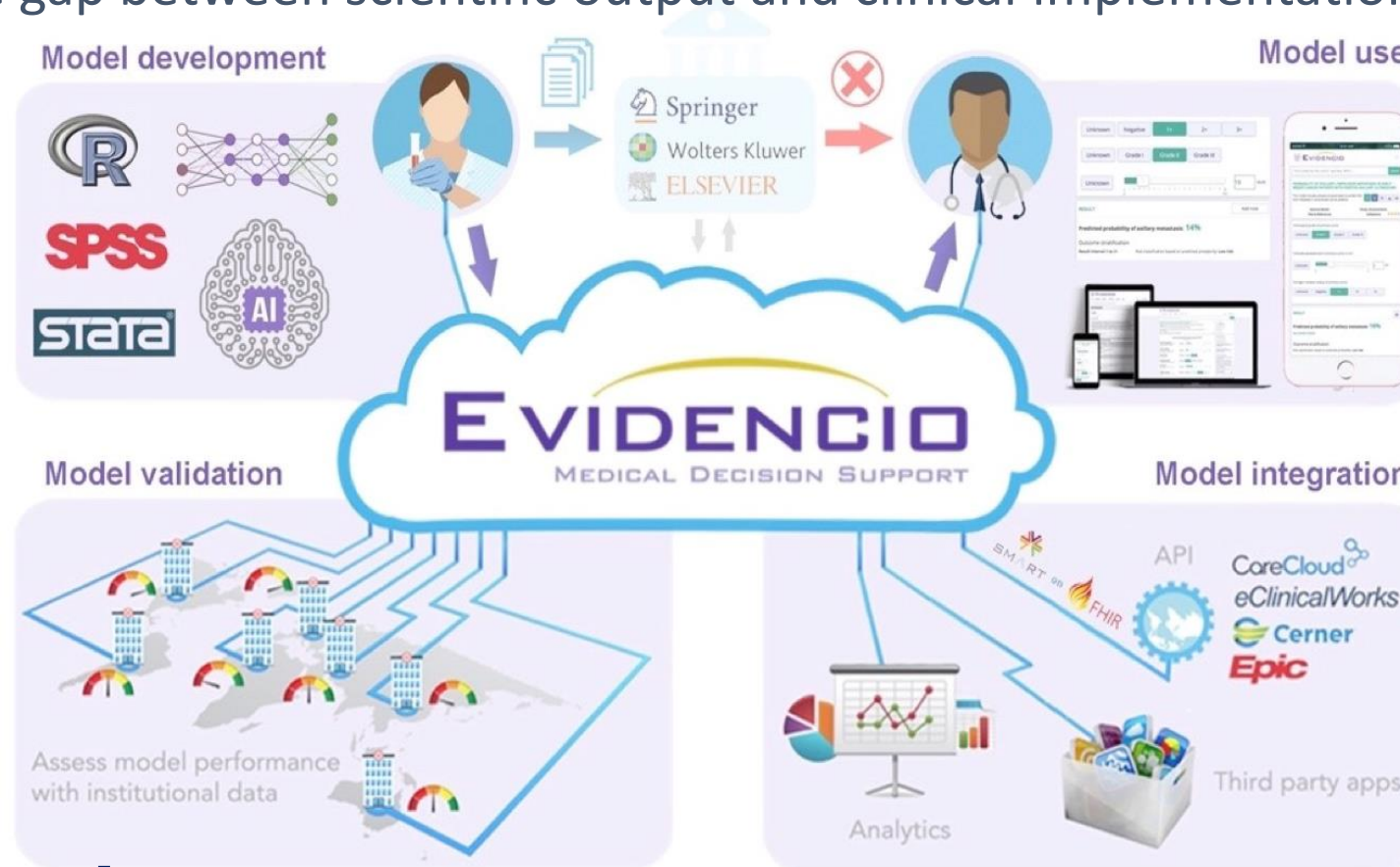
Risk definitions:

- Low risk: < 15%
- Intermediate risk: 15% - 25%
- High risk: > 25%

Example of nomogram usage

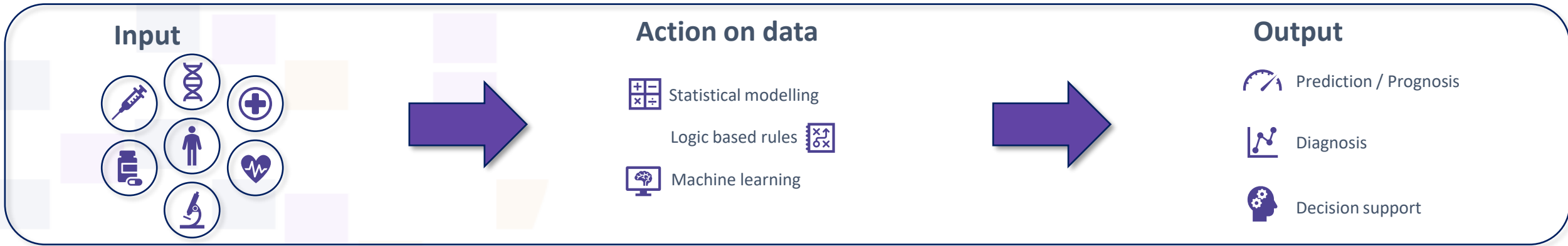
The Evidencio platform

Bridging the gap between scientific output and clinical implementation



Publication of the MDR and the IVDR

EU regulation 2017/745 & EU regulation 2017/746




Intended purpose for the benefit of an individual patient => Medical Device

CE
2797 **Certification required!**



Quality & information security management system certifications

bsi.




By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: **Evidencio B.V.**

Certificate
K-0203301 / 4

Issued on	2023-12-15	Page	1 of 1
First issue	2020-12-15	Valid until	2026-12-14
Replaces	K-0203301/3		

NEN7510-1: 2017+A1:2020

With this certificate Kiwa confirms that the management system implemented by
Evidencio B.V.

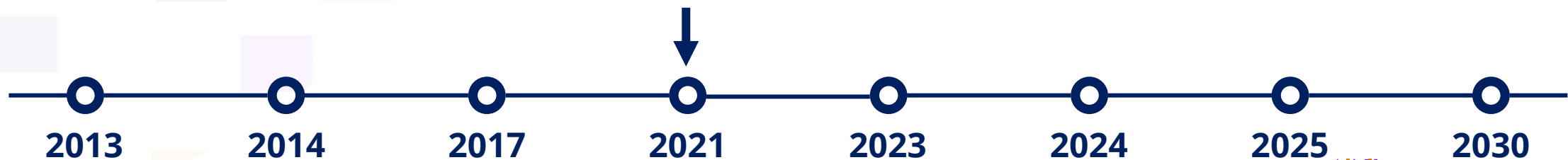


Certificate
K-0205807 / 2

Issued on	2023-12-15	Page	1 of 1
First issue	2020-12-15	Valid until	2025-10-31
Replaces	K-0205807/1		

ISO 27001:2017

With this certificate Kiwa confirms that the management system implemented by
Evidencio B.V.



MDR certificate received for first 4 algorithms

EVIDENCIO MEDICAL DECISION SUPPORT
Dashboard Models Validations About Pricing Admin

The ABC Stroke Risk Score

LOT V-3.10-2187.23.11.03 **CE**
2797

UDI (01)08720299526402(8012)v3.10(4326)231103(240)2187

Download the [User manual](#) and consult the [Intended purpose](#).

Troponin biomarker
Indicate which Troponin biomarker is available to you

Prior stroke
Indicate whether the patient previously suffered from a stroke or transient ischemic attack (TIA)

Age
Age of the patient in years
22 95 years

NT-proBNP ⓘ
The NT-proBNP levels were determined with sandwich immunoassays on the Cobas Analytics e601 Immunoanalyzers (Roche Diagnostics, Mannheim, Germany) according to manufacturer in...
5 21000 ng/L

Predict result for

bsi.



By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

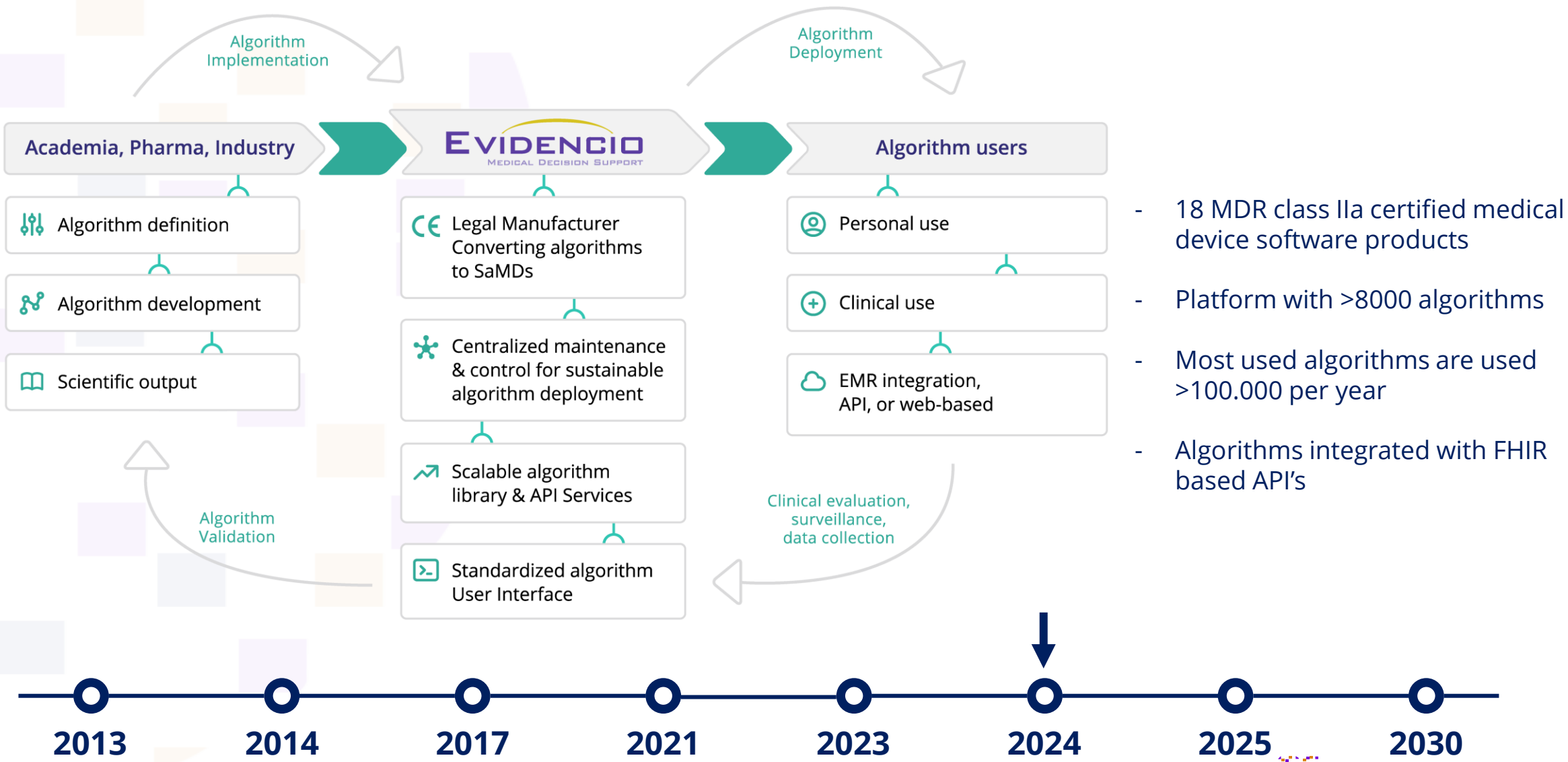
MDR 761407 R000

Device Schedule: Class IIa, Custom-made and other devices



2797

Bridging the gap between scientific output and clinical implementation



- 18 MDR class IIa certified medical device software products
- Platform with >8000 algorithms
- Most used algorithms are used >100.000 per year
- Algorithms integrated with FHIR based API's

CE-certification: lead time & costs

Evidencio's legal manufacturer as a service benefits

	ISO-13485 certification	ISO-27001 certification	Setting up technical file	Assessment by Notified Body	Algorithm integration	Post-market surveillance	Periodic audits	Algorithm maintenance
DIY*	🕒🕒🕒	🕒🕒🕒	🕒🕒🕒	🕒🕒🕒	🕒🕒🕒	🕒🕒	🕒🕒	🕒🕒🕒
Evidencio	-	-	🕒🕒	🕒	🕒	🕒	🕒	🕒

	🕒	€
DIY*	12 – 18 months	> €200.000,-
Evidencio	6 – 9 months	± €100.000,-

	ISO-13485 certification	ISO-27001 certification	Setting up technical file	Assessment by Notified Body	Algorithm integration	Post-market surveillance	Periodic audits	Algorithm maintenance
DIY*	€€€	€€€	€€€	€€€€	€€€	€€	€€	€€
Evidencio	-	-	€€	€€	€	€	€	€

*DIY = Do it yourself

🕒 **Twice as fast**
 📉 **Half the costs**



Examples of software products provided by Evidencio

Algorithms for imaging analysis



A Class Ulcer Confidence 87.5%

Clinical prediction models & medical calculators

Age 60

Grade I II III

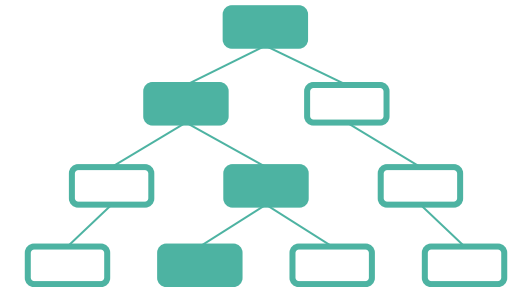
Tumor stage pT1 pT2 pT3

Nodal stage pN0 pN1 pN2 pN3

Multifocality No Yes

5-year locoregional recurrence risk is: **2%**
5-year risk of new primary tumor is: **4%**

Guideline based decision trees to support medical decisions and automatically create patient specific reports.



Recommendation: refer patient to tertiary center for diagnostic assessment



Technical medical organisations collaborating as one team.



Multi disciplinary team of ± 30 employees located in Haaksbergen, the Netherlands



Future perspectives, short term

- **Expanding existing markets for medical device software:**
 - FDA Approval
 - IVDR certification
 - Compliance with the AI act
- **Expanding the number of products**
 - >40 software algorithms certified in 2025
 - Developing the technical documentation of state-of-the-art algorithms
- **Clinical implementation of certified algorithms**
 - Increasing the number of hospitals integrated with Evidencio
 - Continuous improvement of existing software based on clinical needs.

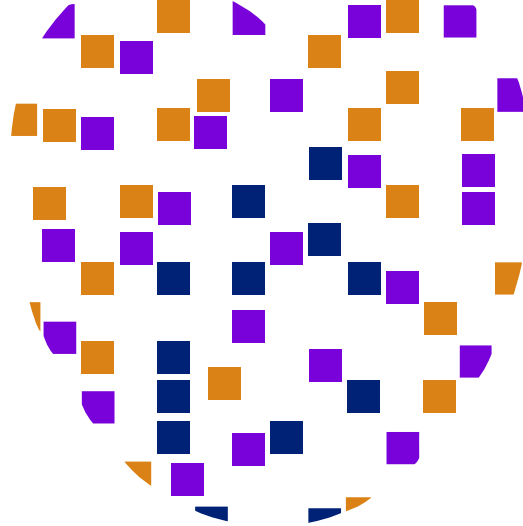


Future perspectives, long term



*The trusted partner for
CE-certified (AI) medical
software devices &
decision support tools*





EVIDENCIO[®]

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