User manual

for the

Briganti Nomogram

Briganti 2012 Nomogram

Briganti 2017 Nomogram

Briganti 2019 Nomogram

Version 3, JUL 2024, in English

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1. The Evidencio platform

The Evidencio platform facilitates the creation, use, validation and implementation of medical prediction models and clinical decision support tools. This User Manual specifically relates to the Briganti Nomogram, which overs the Briganti 2012 Nomogram, the Briganti 2017 Nomogram and the Briganti 2019 Nomogram. The User Manual can also be referred to as the Instructions For Use (IFU).

Throughout this manual CE-marked content and the term medical device are used interchangeably.

2. Disclaimer

Evidencio provides information, models, calculators, equations, and algorithms (tools) intended for use by healthcare professionals. Some of these tools have been certified as CE-medical devices. For such CE-marked content the 'Official Legal Disclaimer for CE-marked content' applies. All other content and tools provided by Evidencio are explicitly only covered by the 'Official Legal Disclaimer for non CE-marked content. Both are available on the Evidencio website: https://www.evidencio.com/disclaimer.

3. Warnings

3.1. Warnings for CE-marked content

Calculations alone should never dictate patient care, and are no substitute for professional judgement. This tool is only to be used by professionals in a clinical setting, and is not for patient use.

Always read the intended use before using this tool.

Always make sure the patient complies with the clinical indications and clinical contra-indications as stated in **paragraphs 6.3.1** and **6.3.2** respectively.

Before reading the result, double check the filled in values to prevent errors.

Results that concern risk percentages, do not guarantee certain outcomes. When there is a risk present, do not expect an event to not occur at all, even if the risk is very small. Conversely, a high risk does not guarantee that an event will occur.

This model is only intended for use in settings where the usage and result of a model are never immediately needed.

No security or privacy-sensitive personal and health-related data is stored after the use of CE-certified Medical Device Software (MDSW) models provided by Evidencio. When using the online platform, any new input, the closing of the browser tab and the refreshing of the page will remove the previously provided input. Only user data regarding which devices are used when and by whom are logged.

4. Device Description Briganti Nomogram

The Briganti Nomogram is intended to support clinical decision making by estimating the risk that an extended Pelvic Lymph Node Dissection (ePLND) and biopsy would identify positive for a tumor in patients with clinically localized prostate cancer (PCa).

The Briganti Nomogram consists of three different mathematical algorithms, described in three different scientific publications, published in 2012, 2017 and 2019. The singular term Briganti Nomogram is used for clarity and brevity when something applies to all 3 versions. Differences between the separate devices will be mentioned when applicable.

The Briganti 2012 Nomogram model predicts the probability of pelvic lymph node invasion for patients undergoing extended pelvic lymphadenectomy based on pretreatment prostate-specific antigen (PSA), clinical stage, primary and secondary biopsy Gleason score, and percentage of positive cores. Biopsy for determination of percentage of positive cores was done through transrectal ultrasound-guided prostate biopsy.

The Briganti 2012 Nomogram was developed by Briganti et al. in a population of 588 patients with clinically localized Prostate Cancer at a single tertiary referral center at the IRCCS Ospedale San Raffaele hospital in Italy between 2006 and

2010. It was externally validated in a variety of situations, including the later development of the Briganti 2017 Nomogram and Briganti 2019 Nomogram, and by Gandaglia et al in 2020 in a population of 487 patients diagnosed via MRI-targeted biopsies plus concomitant systematic biopsy, treated with Radical Prostatectomy (RP) and anatomic ePLND in six European tertiary referral centers (in Bucharest, Ghent, Innsbruck, Munich, Toulouse and Turin.) that had not been included before.

The Briganti 2017 Nomogram model predicts the probability of pelvic lymph node involvement for patients with localized PCa with clinical stage obtained according to digital rectal examination and transrectal ultrasound-guided prostate biopsy. It is an updated version of the Briganti 2012 Nomogram model that also includes the percentages of positive cores with the highest grade and lowest grade.

The Briganti 2017 Nomogram was developed by Gandaglia et al. in a population of 681 patients treated with open or robot-assisted RP and ePLND for localized PCa between January 2011 and July 2016 in the tertiary referral center of the IRCCS Ospedale San Raffaele hospital in Italy. It was externally validated in a variety of situations, including the later development of the Briganti 2019 Nomogram, and by Gandaglia et al. in 2020 in a population of 487 patients diagnosed via MRI-targeted biopsies plus concomitant systematic biopsy, treated with RP and anatomic ePLND in six European tertiary referral centers (in Bucharest, Ghent, Innsbruck, Munich, Toulouse and Turin) that had not been included before.

The 2019 model predicts the probability of pelvic lymph node involvement for patients with Clinically Localized Prostate Cancer Diagnosed with Magnetic Resonance Imaging-targeted and Systematic Biopsies The current model is applicable exclusively to men with a positive MRI-targeted biopsy with concomitant systematic biopsy, as currently indicated by guidelines. Moreover, the risk of LNI should not be estimated using this model for individuals who were diagnosed via systematic biopsy with a negative MRI-targeted biopsy. For these patients, predictive tools developed using data for men diagnosed with systematic biopsy such as the Briganti 2012 Nomogram and Briganti 2017 Nomogram are more suitable.

The Briganti 2019 Nomogram was developed by Gandaglia et al. in a population of 581 patients who underwent MRI-targeted biopsy and RP with ePLND for clinically localized prostate cancer between 2016 and 2018 at five European Tertiary referral centers. It was externally validated by Gandaglia et al. in 2020 in a population of 487 patients diagnosed via MRI-targeted biopsies plus concomitant systematic biopsy, treated with RP and anatomic ePLND in six European tertiary referral centers (in Bucharest, Ghent, Innsbruck, Munich, Toulouse and Turin) that had not been included before.

5. Electronic Label

The electronic label of this device contains the following information:

Name of the device: Briganti Nomogram
Manufacture information: Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands
LOT number:

Briganti 2012 Nomogram: V-2.0-1555.24.07.31
Briganti 2017 Nomogram: V-3.0-1555.24.07.31
Briganti 2019 Nomogram: V-4.0-1555.24.07.31

UDI-PI number:

Briganti 2012 Nomogram: (01)08720938015205(8012)v2.0(4326)240731(240)1555
Briganti 2017 Nomogram: (01)08720938015199(8012)v3.0(4326)240731 (240)1555
Briganti 2019 Nomogram: (01)08720938015182(8012)v4.0(4326)240731 (240)1555

The electronic label can be found on the Evidencio website, see also section **H** and **Figure *5***.

The electronic label on the website further contains the option to download the **User Manual** and **Declaration of conformity** (DoC).

5.1. LOT number

The LOT number indicated the model version, the model identifier, and the model publication date. Publication date is indicated as YY.MM.DD.

5.2. UDI-PI number

Stands for Unique Device Identifier Production Identifier (UDI-PI) number is an international tool that helps users identify and find information on products. Evidencio's UDI-PIs have the following format:

(01)[UDI-DI number](8012)[versionnumber](4326)[releasedate](240)[identificationnumber]

The UDI-DI (Device Identifier) number is a unique numeric code. For each medical device of Evidencio, a unique UDI-DI is ascribed. This UDI-DI is used as an "access key" for information stored in a unique device identification database (UDID). Information on Evidencio's medical devices can be found by searching for the UDI-DI number in the following data base: https://gepir.gs1.org/index.php/search-by-gtin

The version number, also part of the UDI-PI, is linked to one of the 3 device sub-models. Version 2.0 for the Briganti 2012 Nomogram, Version 3.0 for the Briganti 2017 Nomogram, and version 4.0 for the Briganti 2019 Nomogram.

6. Intended Purpose

6.1. Intended Medical Use

The device is intended to be used by professional users who are capable of operating the device and interpreting its results. It can be used to estimate the probability of lymph node involvement in patients with clinically localized Prostate Cancer (PCa). The medical device software (MDSW) includes three algorithms, the Briganti 2012 Nomogram, Briganti 2017 Nomogram, and Briganti 2019 Nomogram algorithms.

The device combines preoperative Prostate Specific Antigen (PSA), Clinical T-stage, primary Gleason Grade, Secondary Gleason Grade and Percentage of positive cores for the 2012 algorithm, preoperative PSA, Clinical T-stage, Biopsy Gleason Grade Group, Percentage of positive cores with highest-grade PCa and percentage of positive cores with lower grade PCA for the 2017 algorithm and Preoperative PSA, clinical stage at mpMRI, maximum lesion diameter at mpMRI, biopsy Gleason grade group at MRI-targeted biopsy and percentage of cores with clinically significant PCa at systematic biopsy for the Briganti 2019 Nomogram algorithm, to predict the risk of pelvic lymph node involvement. What version should be used for a patient depends on the available patient data.

Table 1. Input variables for the Briganti Nomogram

Name	Description	Type	Range (step size)	Units
Briganti 2012 Nomogram				
PSA	Prostate Specific Antigen	Continuous	0-50 (0.1)	ng/ml
Clinical T-stage	Tumor stage	Categorical	Stage T1 Stage T2 Stage T3	
Primary Gleason Grade		Categorical	≤3 ≥4	
Secondary Gleason Grade		Categorical	≤3 ≥4	
Percentage of Positive Cores	Percentage of positive cores taken during transrectal ultrasound-guided prostate biopsy	Continuous	0-100 (0.1)	%
Briganti 2017 Nomogram				
Preoperative PSA	Preoperative Prostate Specific Antigen	Continuous	0-50 (0.1)	ng/ml
Clinical T stage	Tumor stage	Categorical	Clinical Stage T1 Clinical Stage T2 Clinical Stage T3	

Biopsy Gleason Grade group		Categorical	1-2 3 4-5	
Percentage of positive cores with highest-grade PCA		Continuous	0-100 (0.1)	%
Percentage of positive cores with lower grade PCA		Continuous	0-100 (0.1)	%
Briganti 2019 Nomogram				
Preoperative PSA	Preoperative Prostate Specific Antigen	Continuous	0-80 (0.1)	ng/ml
Clinical stage at mpMRI		Categorical	Organ confined Extracapsular extension Seminal vesicle invasion	
Maximum lesion diameter at mpMRI		Continuous	0-45 (1)	mm
Biopsy Gleason grade group at MRI-targeted biopsy		Categorical	1 2 3 4 5	
Percentage of cores with clinically significant PCa at systematic biopsy		Continuous	0-100 (0.1)	%

The device is intended to be used for patients with clinically localized PCa. The result of the device is intended to be reviewed and interpreted by qualified medical specialists only. The device is not intended for use by patients on their own.

The device is not intended to replace clinical decision-making. It can only provide information to the user on the estimation of pelvic lymph node involvement. The user can use this information to support clinical decision-making regarding optimal treatment options. In practice, this typically entails the decision to perform an extended pelvic lymph node dissection.

6.2. Clinical Benefit

The Briganti Nomogram is intended to assist patients with relevant and specified clinical outcome parameters. Concretely, this is achieved by estimating a risk in order to support clinical decision-making aimed at patients with clinically localized prostate cancer, in order to support clinical decision-making regarding patient treatment. Correct functioning of the Briganti Nomogram can result in these clinical benefits:

- The Briganti Nomogram can assist in risk stratification of patients.
- Risk stratification can reduce the burden of (invasive and intensive) medical procedures in patients with low risks, reducing, shortening or avoiding adverse events caused by the procedures.
- Risk stratification can reduce the unnecessary consumption of (scarce) medical resources, decreasing costs and increasing their availability for high risk patients.
- Digital implementation of the algorithm underlying the Briganti Nomogram as a medical device can improve the speed and reliability of calculation. This would further increase the accuracy of the prognosis and by extent increase the chance for the above-mentioned benefits.

6.3. Intended target population and exclusion

The Briganti nomogram is intended to be used only for a specific group of patients, corresponding to the below indications and contra-indications.

6.3.1. Clinical Indications

The Briganti nomogram should be used for patients who meet the following inclusion criteria:

- Patients with clinically localized PCa

6.3.2. Clinical contra-indications

The Briganti nomogram should not be used for patients who meet one or more of the following exclusion criteria:

- Patients with incomplete pathologic or biopsy data required for calculation of (one of the) Briganti Nomogram(s)

6.4. Lifetime, residual risks and side effects

The Briganti nomogram is software, and does not expire. The lifetime is initially set at 5 years from certification, if the state of the art does not change in such a way as to negatively affect the benefit-risk of the device, the lifetime can be extended.

Evidencio has identified a series of risks associated with the use of this model.

The Briganti nomogram is a low-risk device, there are no noticeable risks involved outside of possible mis-estimation of patient risk of Lymph Node Involvement, and all residual risks are accepted.

Most identified risks can be defined into two main groups, depending on their outcome.

a) The risk calculation was wrong or;

b) The MDSW prediction model is inaccessible.

A wrong risk calculation can be the result of erroneous input values or an error in the mathematical calculation. Technical risks, including the erroneous calculations or the inaccessibility due to a technical error, have been mitigated when possible. These measures focused on reducing the risks' probability and severity. Concluding that the risks could not be mitigated further, the residual risks were classified as low-level and acceptable. It should be noted that the use of Evidencio's Medical Device Software is itself a risk mitigation measure, as Evidencio's certified Quality Management System ensures and monitors the reliability of the calculations performed with its certified medical devices.

The Briganti Nomogram does not have any direct side effects relevant for the patient.

6.5. User profile

The Briganti nomogram is intended to be used by Healthcare Professionals or automatically calculated through Evidencio's API. Results shall always be reviewed and interpreted by qualified medical specialists only, in the context of the patient's clinical history and other diagnostic test results. Healthcare professionals do not require additional training prior to the use of the medical device. The device is not intended for use by patients on their own

6.6. Intended use environment

The MDSW can be used as made available on the Evidencio platform in any actively supported web-browser on personal computers, mobile devices, or tablet PCs, and on the mobile app provided by Evidencio. The MDSW can also be used through Evidencio's iFrame representation as an embedded view, provided that the specific Evidencio guidelines for iFrame implementations of this MDSW are adhered to. Automated calculation of the device is enabled through Evidencio's API. The device is only intended for use in healthcare settings where the immediate application and outcomes of the device are not required.

6.7. Versions of the MDSW

The versions of the Briganti Nomogram concerned in this document were developed by Briganti et al. in 2012. Gandaglia et al. in 2017, and Gandaglia et al. in 2019, resulting in the Briganti 2012 Nomogram, Briganti 2017 Nomogram, and Briganti 2019 Nomogram versions respectively. The versions mainly differ in the variables required to calculate the risk of Lymph Node Invasion. The 2017 model adds a precise assessment of cancer involvement within the biopsy core and intraprostatic heterogeneity to the Briganti 2012 nomogram model, while the Briganti 2019 Nomogram model is specifically based on multiparametric magnetic resonance imaging data instead of ultrasound-based data.

6.8. Functioning, physical principle

The MDSW's underlying mathematical formula concerns a logistic regression based statistical model. The acquisition and processing of the data, the analyses to assemble the relevant criteria for the MDSW as well as the setup and refinement

are provided in the instructions for use. Entering the details for an individual in the MDSW initiates the estimation of pelvic lymph node involvement risk.

7. Result interpretation

The primary output of this device is given as a calculated risk of Lymph Node Involvement as a percentage. Because they are different models, the information given to interpret the results is slightly different for each version

Briganti 2012 Nomogram	According to the original derivation paper, using a 5% nomogram cut-off, roughly two-thirds of patients would be spared ePLND, and LNI would be missed in only 1.5%. However, modern guidelines generally recommend a 7% cut-off value.
Briganti 2017 Nomogram	In the derivation dataset, using a 7% cutoff, 471 (69%) ePLNDs would be spared and LNI would be missed only in seven (1.5%) patients.
Briganti 2019 Nomogram	Adoption of this model using a 7% cutoff would avoid approximately 60% of ePLND procedures at the cost of missing only 1.6% of LNI cases.

Conditional information

The provided conditional information shown below

- The calculated risk is 7% or higher. Extended pelvic lymph node dissection is recommended for this patient.
- The calculated risk is lower than 7%. Extended pelvic lymph node dissection can be safely omitted for this patient

Calculations alone should never dictate patient care, and are no substitute for professional judgement. See the Evidencio website for the full disclaimer; https://www.evidencio.com/disclaimer.

8. Additional information

8.1. Details

Model author: T. A. Hueting

Model ID: 1555

	Version number	**Revision date**
Briganti 2012 Nomogram:	2.0	31 July 2024
Briganti 2017 Nomogram:	3.0	31 July 2024
Briganti 2019 Nomogram:	4.0	31 July 2024

Speciality: Oncology, Urology

Model type: Logistic Regression

MeSH terms: Prostate Cancer
Lymphadenectomy

8.2. Study characteristics

8.2.1. Briganti 2012 Nomogram

From derivation study:

The Briganti 2012 Nomogram model was published in 2012, as a routine update to the previous Briganti model to stay up to date. The patient characteristics for the data used to derive the nomogram is included below:

Clinical and pathologic data were prospectively gathered for 588 patients treated with RP and ePLND between September 2006 and October 2010 at the San Farraele Scientific institute's hospital. All patients were subjected to detailed preoperative evaluation consisting of prostate-specific antigen (PSA) assay (Abbott AxSYM PSA assay; Abbott Laboratories, Abbott Park, IL, USA), clinical stage assessed by the attending urologist (according to the 2002 American Joint Committee on Cancer staging system), and

transrectal ultrasound-guided prostate biopsy. In addition to Gleason sum, the total number of cores taken as well as the number and the percentage of positive cores were recorded for each patient. All men had histologically proven PCa and underwent RP preceded by ePLND, regardless of PCa characteristics.

Table 1. This table contains information on the patient group data used to derive the Briganti 2012.

NAME	Q1	MEDIAN	Q3	UNIT
Age at surgery (pN0 patients)	60.3	65.2	70.6	years
Age at surgery (pN1 patients)	60.3	65.3	69.5	years
Preoperative PSA (pN0 patients)	4.7	7.5	8.7	ng/ml
Preoperative PSA (pN1 patients)	6.2	12.8	12.5	ng/ml
Cores taken overall (pN0 patients)	14	17	24	cores
Cores taken overall (pN1 patients)	12	15.5	18	cores
Positive cores overall (pN0 patients)	3	6	10	cores
Positive cores overall (pN1 patients)	6	10.5	14	cores
Percentage of positive cores overall (pN0 patients)	16.7	33.3	57.1	%
Percentage of positive cores overall (pN1 patients)	51.0	78.6	100	%
Lymph nodes removed (pN0 patients)	15	19	25	nodes
Lymph nodes removed (pN1 patients)	16	21	28	nodes
Positive lymph nodes	1	2	3	nodes

Table 2. This table contains categorical characteristics on the patient group data used to derive the Briganti 2012

NAME	SUBSET / GROUP	NR. OF PATIENTS
Lymph node involvement	pN0	539
Lymph node involvement	pN1	49
Clinical stage (pN0 patients)	T1	360
Clinical stage (pN0 patients)	T2	164
Clinical stage (pN0 patients)	T3	15
Clinical stage (pN1 patients)	T1	13
Clinical stage (pN1 patients)	T2	20
Clinical stage (pN1 patients)	T3	16
Primary Gleason Grade pN0	≤3	466
Primary Gleason Grade pN0	≥4	73
Secondary Gleason grade pN0	≤3	466
Secondary Gleason grade pN0	≥4	73
Primary Gleason grade pN1	≤3	22
Primary Gleason grade pN1	≥4	27
Secondary Gleason grade pN1	≤3	20
Secondary Gleason grade pN1	≥4	29
Pathologic stage pN0	pT2	427
Pathologic stage pN0	pT3a	84
Pathologic stage pN0	pT3b	28
Pathologic stage pN0	pT4	0
Pathologic stage pN1	pT2	4
Pathologic stage pN1	pT3a	13
Pathologic stage pN1	pT3b	30
Pathologic stage pN1	pT4	2
Pathologic Gleason score pN0	2-6	222
Pathologic Gleason score pN0	7	260
Pathologic Gleason score pN0	8-10	43
Pathologic Gleason score pN0	missing	14
Pathologic Gleason score pN1	2-6	1
Pathologic Gleason score pN1	7	22
Pathologic Gleason score pN1	8-10	20
Pathologic Gleason score pN1	Missing	6

8.2.2. Briganti 2017 Nomogram

From derivation study:

After Institutional Review Board approval, clinical and pathologic data were prospectively collected for 2872 patients treated with open or robot-assisted RP and ePLND for localized PCa between January 2011 and July 2016 at a single tertiary referral center. Patients with complete data who underwent centralized biopsy specimens review performed by two high-volume dedicated uropathologists selected (n = 681). No patients received neoadjuvant hormonal therapy. All cases were performed by six surgeons with at least 200 cases at the beginning of data collection who were trained by the same surgeon and applied the same anatomical template for ePLND. The fibrofatty tissue along the external iliac vein was dissected, the lateral limit being the genitofemoralis nerve. Proximally, an ePLND was performed up to and included the crossing between the ureter and common iliac vessels. Lymph nodes along as well as medially and laterally to the internal iliac vessels were removed. All fibrofatty tissue within the obturator fossa was removed, and the Marcille's triangular lumbosacral fossa was dissected free. All specimens were submitted for pathologic evaluation in multiple packages according to their anatomical location and were evaluated by dedicated uropathologists according to a previously described methodology

Table 3. This table contains information on the patient group data used to derive the Briganti 2017.

NAME	Q1	MEDIAN	Q3	UNIT
Age at surgery (pN0 patients)	60	65	70	years
Age at surgery (pN1 patients)	59	65	71	years
Preoperative PSA (pN0 patients)	4.5	6.4	7.9	ng/ml
Preoperative PSA (pN1 patients)	6.1	10.8	21	ng/ml
Cores taken overall (pN0 patients)	12	14	20	cores
Cores taken overall (pN1 patients)	12	14	18	cores
Percentage of positive cores overall (pN0 patients)	14.3	31.6	50.0	%
Percentage of positive cores overall (pN1 patients)	42.8	62.5	85.7	%
Positive cores with highest-grade PCa (pN0 patients)	13.2	25	45.0	%
Positive cores with highest-grade PCa (pN1 patients)	31.9	50	81.8	%
Positive cores with lower-grade PCa (pN0 patients)	16.6	25	41.6	%
Positive cores with lower-grade PCa (pN1 patients)	23.3	33.3	51.8	%
Lymph nodes removed (pN0 patients)	8	15	21	nodes
Lymph nodes removed (pN1 patients)	15	20	27	nodes
Positive lymph nodes	1	1	4	nodes
Year of Surgery	2013	2014	2015	Years
Maximum percentage of single core involvement with highest-grade PCa pN0	10	30	60	%
Maximum percentage of single core involvement with highest-grade PCa pN1	40	75	90	%
Maximum percentage of single core involvement with lower-grade PCa pN0	20	40.9	61.1	%
Maximum percentage of single core involvement with lower-grade PCa pN1	31.2	76.8	93.4	%
Total tumor length pN0	0.35	1.3	2.93	cm
Total tumor length pN1	2.6	4.9	8.9	cm
Total biopsy length pN0	16.4	20.0	26.0	cm
Total biopsy length pN1	17.1	20.0	23.4	cm
Percentage of tumor in biopsy cores pN0	1.7	6.8	15.8	%
percentage of tumor in biopsy cores pN1	11.3	27.8	45.6	%
Tumor length of highest-grade PCa pN0	0.3	1.12	2.7	cm
Tumor length of highest-grade PCA pN1	4.2	2.0	7.8	cm

Tumor length of lower-grade PCa pN0	0.41	0.9	1.95	cm
Tumor length of lower-grade PCa pN1	1.18	2.1	4.51	cm
Maximum percentage of single core involvement with lower-grade PCa pN0	20	40.9	61.1	%
Maximum percentage of single core involvement with lower-grade PCa pN1	31.2	76.8	93.4	%
Total tumor length pN0	0.35	1.3	2.93	cm
Total tumor length pN1	2.6	4.9	8.9	cm

Table 4. This table contains categorical characteristics on the patient group data used to derive the Briganti 2017

NAME	SUBSET / GROUP	NR. OF PATIENTS
Lymph node involvement	pN0	602
Lymph node involvement	pN1	79
Clinical stage (pN0 patients)	T1	357
Clinical stage (pN0 patients)	T2	222
Clinical stage (pN0 patients)	T3	23
Clinical stage (pN1 patients)	T1	18
Clinical stage (pN1 patients)	T2	42
Clinical stage (pN1 patients)	T3	19
Biopsy Gleason grade group (pN0 patients)	1	260
Biopsy Gleason grade group (pN0 patients)	2	233
Biopsy Gleason grade group (pN0 patients)	3	65
Biopsy Gleason grade group (pN0 patients)	4	33
Biopsy Gleason grade group (pN0 patients)	5	11
Biopsy Gleason grade group (pN1 patients)	1	1
Biopsy Gleason grade group (pN1 patients)	2	14
Biopsy Gleason grade group (pN1 patients)	3	28
Biopsy Gleason grade group (pN1 patients)	4	15
Biopsy Gleason grade group (pN1 patients)	5	21
Surgical technique	Open	205
Surgical technique	Robot-assisted	476
Gleason grade group on final pathology (pN0 patients)	1	130
Gleason grade group on final pathology (pN0 patients)	2	272
Gleason grade group on final pathology (pN0 patients)	3	128
Gleason grade group on final pathology (pN0 patients)	4	26
Gleason grade group on final pathology (pN0 patients)	5	46
Gleason grade group on final pathology (pN1 patients)	1	6
Gleason grade group on final pathology (pN1 patients)	2	7
Gleason grade group on final pathology (pN1 patients)	3	12
Gleason grade group on final pathology (pN1 patients)	4	13
Gleason grade group on final pathology (pN1 patients)	5	41
Pathologic stage (pN0 patients)	pT2	423
Pathologic stage (pN0 patients)	pT3a	153
Pathologic stage (pN0 patients)	pT3b/pT4	24
Pathologic stage (pN1 patients)	pT2	4
Pathologic stage (pN1 patients)	pT3a	26
Pathologic stage (pN1 patients)	pT3b/pT4	49
Positive surgical margins	pN0 patients	90
Positive surgical margins	pN1 patients	41
Site of LNI	Obturator fossa	42
Site of LNI	Internal iliac region	20
Site of LNI	External iliac region	34
Site of LNI	Common iliac region	9
Site of LNI	Presacral area	7

8.2.3. Briganti 2019 Nomogram

From derivation study:

After institutional review board approval, 581 patients who underwent MRI-targeted biopsy and radical prostatectomy (RP) with extended Pelvic Lymph Node Dissection (ePLND) between 2016 and 2018 at five European tertiary referral centers were retrospectively identified. mpMRI and MRI-targeted biopsies were routinely recommended to patients with a clinical suspicion of PCa according to the judgment of the treating physician. Only patients with a positive MRI-targeted biopsy were selected (n = 516). Among those, patients with incomplete biopsy or pathologic data (n = 19) were excluded. This resulted in a final population of 497 patients.

No patients received neoadjuvant hormonal therapy. Surgery was routinely proposed as a treatment option at each center. The decision to perform RP was left to the clinical judgment of the treating physician after discussion with each patient regarding the potential benefits and side effects of all available treatment modalities for the management of localized PCa. Only patients who underwent anatomically defined ePLND with removal of the obturator, internal iliac, and external iliac lymph nodes were included. All procedures were performed by high-volume surgeons at referral institutions. All specimens were submitted for pathologic evaluation in multiple packages and were evaluated by dedicated uropathologists.

Table 5. This table contains information on the patient group data used to derive the Briganti 2019.

NAME	Q1	MEDIAN	Q3	UNIT
Age at surgery (pN0 patients)	60	65	70	years
Age at surgery (pN1 patients)	60	64	71	years
Preoperative PSA (pN0 patients)	5.1	7.2	11	ng/ml
Preoperative PSA (pN1 patients)	6.7	11	21	ng/ml
Prostate volume (pN0 patients)	33	43	55	ml
Prostate volume (pN1 patients)	34	48	59	ml
Maximum index lesion diameter on mpMRI (pN0 patients)	9	10	14	mm
Maximum index lesion diameter on mpMRI	10	15	18	mm
Cores taken overall (pN0 patients)	14	16	18	cores
Cores taken overall (pN1 patients)	14	16	18	cores
Positive cores overall (pN0 patients)	3	5	8	cores
Positive cores overall (pN1 patients)	9	5	12	cores
Percentage of positive cores overall (pN0 patients)	20	33	50	%
Percentage of positive cores overall (pN1 patients)	36	55	80	%
Positive cores with highest-grade PCa (pN0 patients)	12	20	38	%
Positive cores with highest-grade PCa (pN1 patients)	24	40	60	%
Positive cores with lower-grade PCa (pN0 patients)	8	16	27	%
Positive cores with lower-grade PCa (pN1 patients)	10	21	30	%
Systematic cores taken (pN0 patients)	10	12	15	cores
Systematic cores taken (pN1 patients)	10	12	16	cores
Cores with csPCa on systematic biopsy (pN0 patients)	0	12	37	%
Cores with csPCa on systematic biopsy (pN1 patients)	17	42	76	%
Lymph nodes removed (pN0 patients)	10	15	20	nodes
Lymph nodes removed (pN1 patients)	13	17	24	nodes
Positive lymph nodes	1	1	2	nodes

Table 6. This table contains categorical characteristics on the patient group data used to derive the Briganti 2019

NAME	SUBSET / GROUP	NR. OF PATIENTS
Lymph node involvement	pN0	435
Lymph node involvement	pN1	62
Clinical stage (pN0 patients)	T1	335
Clinical stage (pN0 patients)	T2	96
Clinical stage (pN0 patients)	T3	4
Clinical stage (pN1 patients)	T1	30
Clinical stage (pN1 patients)	T2	21
Clinical stage (pN1 patients)	T3	11
PI-RADS score (pN0 patients)	3	121
PI-RADS score (pN0 patients)	4	235
PI-RADS score (pN0 patients)	5	79
PI-RADS score (pN1 patients)	3	4
PI-RADS score (pN1 patients)	4	26
PI-RADS score (pN1 patients)	5	32
Number of PI-RADS ≥3 lesions on mpMRI (pN0 patients)	1	299
Number of PI-RADS ≥3 lesions on mpMRI (pN0 patients)	2	91
Number of PI-RADS ≥3 lesions on mpMRI (pN0 patients)	3	27
Number of PI-RADS ≥3 lesions on mpMRI (pN0 patients)	≥4	18
Number of PI-RADS ≥3 lesions on mpMRI (pN1 patients)	1	38
Number of PI-RADS ≥3 lesions on mpMRI (pN1 patients)	2	20
Number of PI-RADS ≥3 lesions on mpMRI (pN1 patients)	3	3
Number of PI-RADS ≥3 lesions on mpMRI (pN1 patients)	≥4	1
Clinical stage on mpMRI (pN0 patients)	Organ-confined	358
Clinical stage on mpMRI (pN0 patients)	Extracapsular extension	49
Clinical stage on mpMRI (pN0 patients)	Seminal vesicle invasion	13
Clinical stage on mpMRI (pN1 patients)	Organ-confined	29
Clinical stage on mpMRI (pN1 patients)	Extracapsular extension	19
Clinical stage on mpMRI (pN1 patients)	Seminal vesicle invasion	14
Biopsy grade group overall (pN0 patients)	1	55
Biopsy grade group overall (pN0 patients)	2	236
Biopsy grade group overall (pN0 patients)	3	78
Biopsy grade group overall (pN0 patients)	4	45
Biopsy grade group overall (pN0 patients)	5	21
Biopsy grade group overall (pN1 patients)	1	1
Biopsy grade group overall (pN1 patients)	2	15
Biopsy grade group overall (pN1 patients)	3	16
Biopsy grade group overall (pN1 patients)	4	15
Biopsy grade group overall (pN1 patients)	5	15
Grade group on MRI-targeted biopsy (pN0 patients)	1	72
Grade group on MRI-targeted biopsy (pN0 patients)	2	225
Grade group on MRI-targeted biopsy (pN0 patients)	3	72
Grade group on MRI-targeted biopsy (pN0 patients)	4	46
Grade group on MRI-targeted biopsy (pN0 patients)	5	20
Grade group on MRI-targeted biopsy (pN1 patients)	1	1
Grade group on MRI-targeted biopsy (pN1 patients)	2	15
Grade group on MRI-targeted biopsy (pN1 patients)	3	16
Grade group on MRI-targeted biopsy (pN1 patients)	4	17
Grade group on MRI-targeted biopsy (pN1 patients)	5	13
Target cores taken on MRI-targeted biopsy (pN0 patients)	2	165
Target cores taken on MRI-targeted biopsy (pN0 patients)	3	94
Target cores taken on MRI-targeted biopsy (pN0 patients)	4	77
Target cores taken on MRI-targeted biopsy (pN0 patients)	≥5	99
Target cores taken on MRI-targeted biopsy (pN1 patients)	2	27
Target cores taken on MRI-targeted biopsy (pN1 patients)	3	18
Target cores taken on MRI-targeted biopsy (pN1 patients)	4	10
Target cores taken on MRI-targeted biopsy (pN1 patients)	≥5	7
Positive cores on MRI-targeted biopsy (pN0 patients)	1	111
Positive cores on MRI-targeted biopsy (pN0 patients)	2	173
Positive cores on MRI-targeted biopsy (pN0 patients)	3	69
Positive cores on MRI-targeted biopsy (pN0 patients)	≥4	82
Positive cores on MRI-targeted biopsy (pN1 patients)	1	5
Positive cores on MRI-targeted biopsy (pN1 patients)	2	32

Positive cores on MRI-targeted biopsy (pN1 patients)	3	16
Positive cores on MRI-targeted biopsy (pN1 patients)	≥4	9
Grade group on systematic biopsy (pN0 patients)	Negative	80
Grade group on systematic biopsy (pN0 patients)	1	100
Grade group on systematic biopsy (pN0 patients)	2	171
Grade group on systematic biopsy (pN0 patients)	3	44
Grade group on systematic biopsy (pN0 patients)	4	25
Grade group on systematic biopsy (pN0 patients)	5	15
Grade group on systematic biopsy (pN1 patients)	Negative	4
Grade group on systematic biopsy (pN1 patients)	1	6
Grade group on systematic biopsy (pN1 patients)	2	14
Grade group on systematic biopsy (pN1 patients)	3	15
Grade group on systematic biopsy (pN1 patients)	4	9
Grade group on systematic biopsy (pN1 patients)	5	14
Surgical technique	Open	43
Surgical technique	Robot-assisted	454
Gleason grade group on final pathology (pN0 patients)	1	15
Gleason grade group on final pathology (pN0 patients)	2	218
Gleason grade group on final pathology (pN0 patients)	3	147
Gleason grade group on final pathology (pN0 patients)	4	22
Gleason grade group on final pathology (pN0 patients)	5	30
Gleason grade group on final pathology (pN1 patients)	1	0
Gleason grade group on final pathology (pN1 patients)	2	3
Gleason grade group on final pathology (pN1 patients)	3	25
Gleason grade group on final pathology (pN1 patients)	4	4
Gleason grade group on final pathology (pN1 patients)	5	30
Pathologic stage (pN0 patients)	pT2	215
Pathologic stage (pN0 patients)	pT3a	180
Pathologic stage (pN0 patients)	pT3b/pT4	40
Pathologic stage (pN1 patients)	pT2	3
Pathologic stage (pN1 patients)	pT3a	20
Pathologic stage (pN1 patients)	pT3b/pT4	39
Positive surgical margins	pN0 patients	103
Positive surgical margins	pN1 patients	40

8.3. Supporting publication & Related files

Several relevant studies, such as the original derivation study by Briganti and Gandaglia are contained in **Table 7**. These publications have tags to identify their link with the model. Examples of relevant tags are; “Peer review”, “Internal validation”, “External validation”, and “TRIPOD”. Publications that have the tags: “Internal validation” or “External validation”, contain data on the performance characteristics of the device.

Table 7. Overview of selection of supporting publications & Related files.

Derivation Study Briganti 2012	**Updated Nomogram Predicting Lymph Node Invasion in Patients with Prostate Cancer Undergoing Extended Pelvic Lymph Node Dissection: The Essential Importance of Percentage of Positive Cores** *Alberto Brigant , Alessandro Larcher, Firas Abdollah, Umberto Capitanio, Andrea Gallina, Nazareno Suardi, Marco Bianchi, Maxine Sun, Massimo Freschi, Andrea Salonia, Pierre Karakiewicz, Patrizio Rigatti, Francesco Montorsi* *https://www.sciencedirect.com/science/article/abs/pii/S0302283811012309* 10.1016/j.eururo.2011.10.044
Derivation Study Briganti 2017	**Development and Internal Validation of a Novel Model to Identify the Candidates for Extended Pelvic Lymph Node Dissection in Prostate Cancer** *Gandaglia, G., Fossati, N., Zaffuto, E., Bandini, M., Dell'Oglio, P., Bravi, C. A., Fallara, G., Pellegrino, F., Nocera, L., Karakiewicz, P. I., Tian, Z., Freschi, M., Montironi, R., Montorsi, F., & Briganti, A.* *https://www.sciencedirect.com/science/article/abs/pii/S0302283817302804?via%3Dihub* 10.1016/j.eururo.2017.03.049

Derivation Study Briganti 2019	**A Novel Nomogram to Identify Candidates for Extended Pelvic Lymph Node Dissection Among Patients with Clinically Localized Prostate Cancer Diagnosed with Magnetic Resonance Imaging-targeted and Systematic Biopsies** *Gandaglia, G., Ploussard, G., Valerio, M., Mattei, A., Fiori, C., Fossati, N., Stabile, A., Beauval, J. B., Malavaud, B., Roumiguié, M., Robesti, D., Dell'Oglio, P., Moschini, M., Zamboni, S., Rakauskas, A., De Cobelli, F., Porpiglia, F., Montorsi, F., Briganti, A.* *https://www.europeanurology.com/article/S0302-2838(18)30753-X/abstract* 10.1016/j.eururo.2018.10.012
Validation Study:	**External Validation of the 2019 Briganti Nomogram for the Identification of Prostate Cancer Patients Who Should Be Considered for an Extended Pelvic Lymph Node Dissection** *Gandaglia, G., Martini, A., Ploussard, G., Fossati, N., Stabile, A., De Visschere, P., Borgmann, H., Heidegger, I., Steinkohl, F., Kretschmer, A., Marra, G., Mathieu, R., Surcel, C., Tilki, D., Tsaur, I., Valerio, M., Van den Bergh, R., Ost, P., Gontero, P., Montorsi, F., … EAU-YAU Prostate Cancer Working Group* *https://www.sciencedirect.com/science/article/abs/pii/S0302283820301986* 10.1016/j.eururo.2020.03.023

8.4. Release notes

The release notes for each publicly available version of the device can be found on the Evidencio website page for the Briganti Nomogram: https://www.evidencio.com/models/show/1555, selecting the correct device, and clicking on Release Notes. It is recommended to read these notes after a version update to see if these changes are relevant to you.

9. Implementation of the model through an API

The Briganti Nomogram can be used through Evidencio's API to allow for (automated) calculation of the risk of Lymph Node Invasion. In the case of use of the MDSW through the API, the user should take into account the different inputs for the model, in order to properly interpret the results. Furthermore, the information contained within this user manual, specifically chapters 3-8, should be read and understood by the user.

Instruction on how to implement the API within a system are included in a separate document that is made available to the party performing the technical implementation.

When using the MDSW through the API, the warnings and descriptions given in this document all apply, as does the additional information. The information for use included in this document regards both use through the website as well as use through the API, as long as the API is properly implemented. The API is only intended for authorized users.

10. Using the model on the Evidencio website

Using the tool on the Evidencio website, requires a stable internet connection. The tool was tested on the following browsers and will run on these versions and higher;

- Personal computers or laptops using the following browsers:
  - Safari (version 17.5 and higher)
  - Chrome (version 126.0.6478.127 and higher)
  - Firefox (version 128.0 and higher)
  - Edge (version 126.0.2592.102 and higher)
- Tablets or smartphones running on the next operating systems:
  - IOS (version 17.5.1 and higher)
  - Android (version 13 and higher)

Correct functioning of the tool with earlier versions of these browsers cannot be guaranteed.

The medical device cannot be used in combination with Internet Explorer. The personal computers, laptops, tablets or smartphones used should at least be able to have an internet connection and use the browsers mentioned above. The minimal screen resolution should be 800x600.

Furthermore, the model may be used through the Evidencio iFrame representation of the calculator, as an embedded view, provided that the specific Evidencio guidelines for iFrame implementations of that model are adhered to.

The Evidencio MDSW models can be used with any browser settings that don't distort the regular display of websites, with a 50% to 500% zoom rate, and at a display resolution starting from 800x600. However, factory recommended browser settings, 100% zoom rate and regular display resolution are recommended.

The MDSW is intended for authorised users only, and should not be used by unauthorised personnel.

This model is only intended for use in settings where the usage and result of a model are never immediately needed.

10.1. General modelling landing page

The medical device model on the Evidencio platform is shown in **Figure 1**. The model landing page contains the following sections, that are indicated in **Figure 1**.

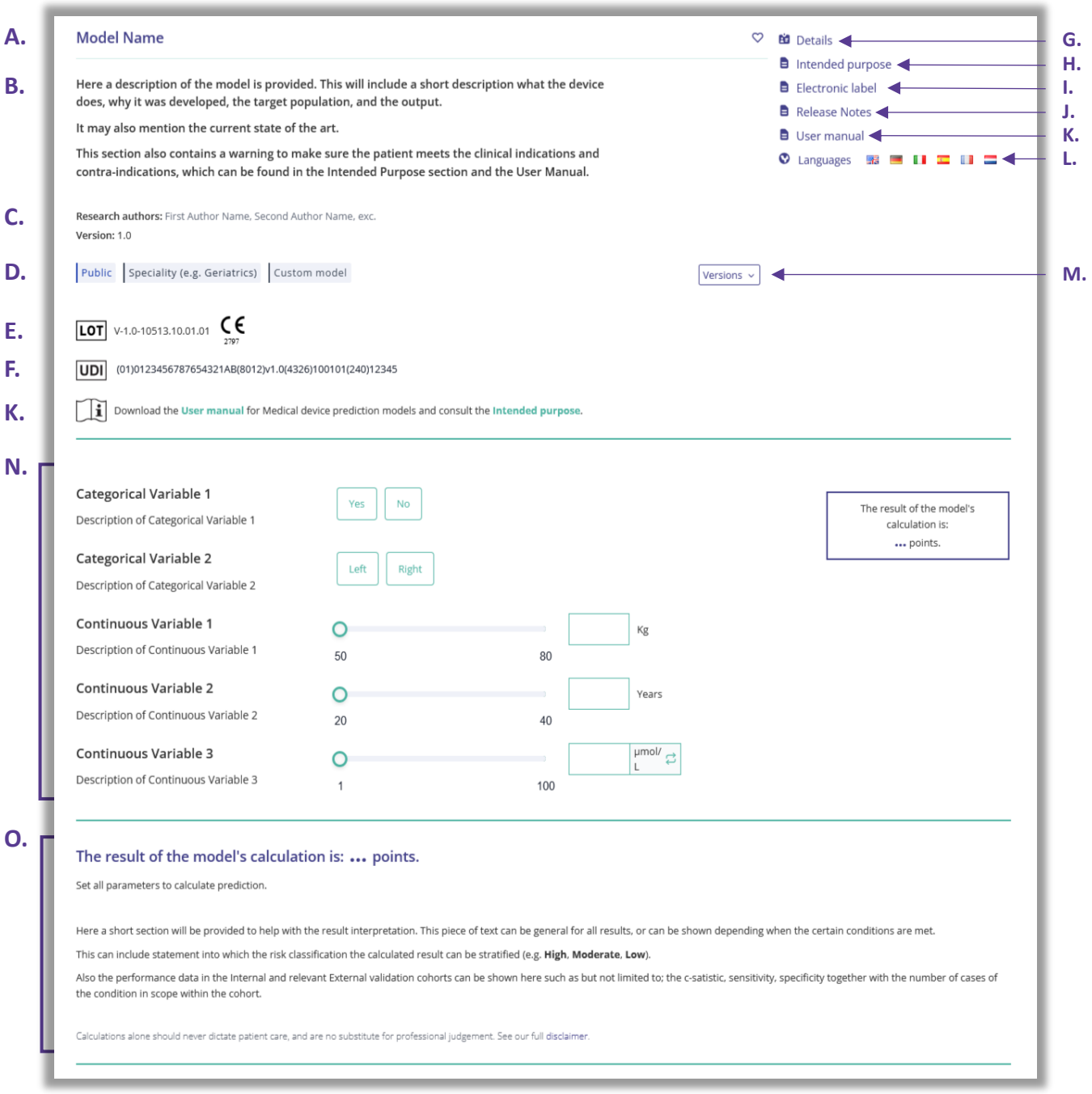

Figure 1. Example of a model landing page on the Evidencio website.

A. Model title

This is the title and name of the model

B. Model description

This is a short description of the model.

C. Research Authors

These are the research authors of the paper that originally published the model.

D. Model tags

These are the tags that are assigned to the model. Evidencio has the following status tags: “Draft”, “Public”, “Private”, “Under review”. Evidencio has the following model type tags: “Composite model”, “Sequential model”, “API model”. Evidencio has the following calculation method tags: “Linear model”, “Logistic regression”, “Cox regression”, “RScript” and “Custom model”. Next to this, there are tags that indicate the specialty e.g. “Cardiology”.

E. LOT number

The LOT number indicated the model version, the model identifier, and the model publication date. Publication date is indicated as YY.MM.DD.

(Additionally, the CE mark is displayed next to the LOT number. This way, medical devices can be easily recognized.)

F. UDI-PI number

The UDI-PI number is an international tool that helps users identify and find information on products. UDI stands for Unique Device Identifier and PI stands for Production Identifier. Evidencio’s UDIs have the following format:

(01)[UDI-DI number](8012)[versionnumber](4326)[releasedate](240)[identificationnumber]

The UDI-DI number is a unique numeric code. For each medical device of Evidencio, a unique UDI-DI is ascribed. It is used as an “access key” for information stored in a unique device identification database (UDID). Information on Evidencio’s medical devices can be found by searching for the UDI-DI number in the following data base:
https://gepir.gs1.org/index.php/search-by-gtin

The version number, also part of the UDI-PI, is linked to one of the 3 device models. Version 2.X for the Briganti 2012 Nomogram, Version 3.X for the Briganti 2017 Nomogram and Version 4.X for the Briganti 2019 Nomogram.

G. Details button

On the top right of the model page, several clickable buttons are displayed that show a pop-up when clicked. The first button opens a pop-up concerning additional information about the model. This pop-up has three sections: Details, Study characteristics and Supporting publications & related files.

Details

The first part of the additional information concerns the details of the model as shown in **Figure 2**. This section may show the calculation if it is built as a mathematical formula and, if applicable, shows the conditions at which certain formulas are used.

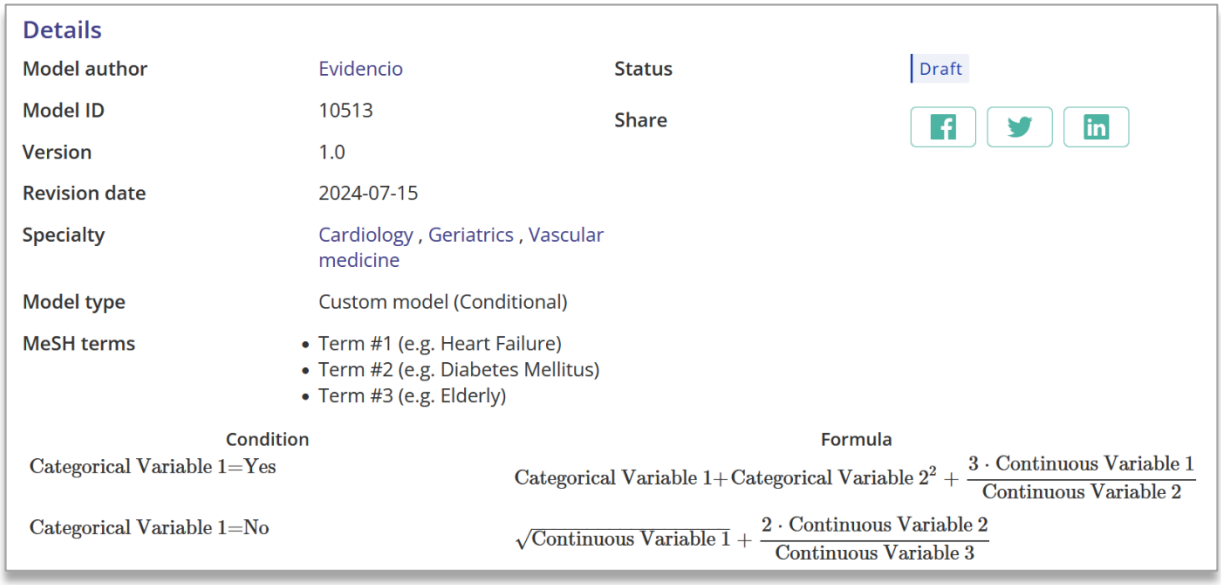

Figure 2. Example of first part of detail section.

Study Characteristics

Below the 'Details section' the section labelled 'Study characteristics' provides information on the characteristics of the patient data used to derive and validate the model. Additional information is provided on the methods used to develop and/or validate the model. An example of the Study characteristics section can be seen in **Figure 3**.

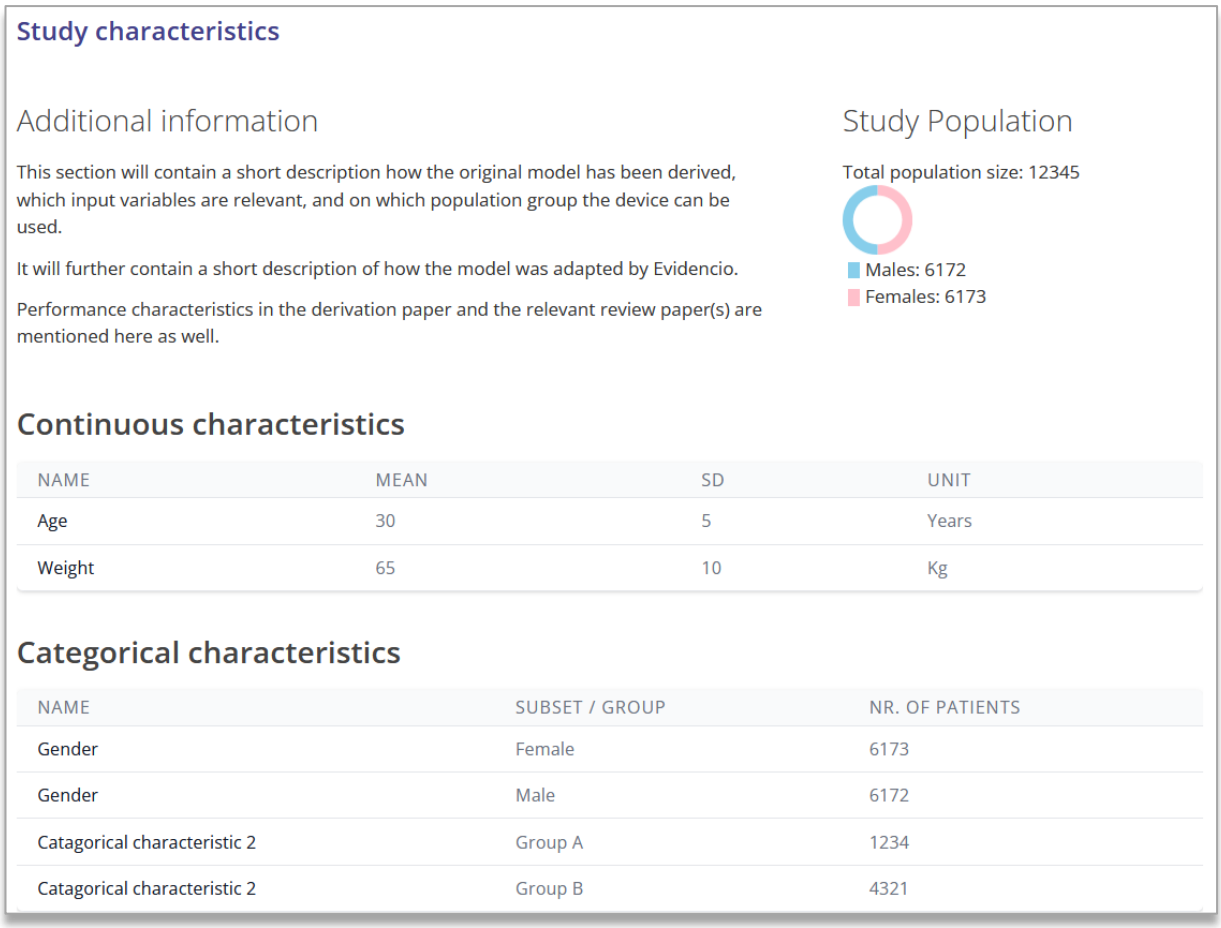

Figure 3. Example of the study characteristics section under the Details tab.

Supporting publications & Related files

An important part of the Study characteristics is the information on Supporting publications and related files. These sections can be found at the bottom of the Details-pop-up as shown in **Figure 4**. Tags are attached to the different files to identify their link with the model. Examples of relevant tags are a.o.; "Peer review", "Internal validation", "External validation", and "TRIPOD". Publications that have the tags: "Internal validation" or "External validation", contain the performance characteristics of the device. Figures and tables which help to interpreted the results may also be provided here.

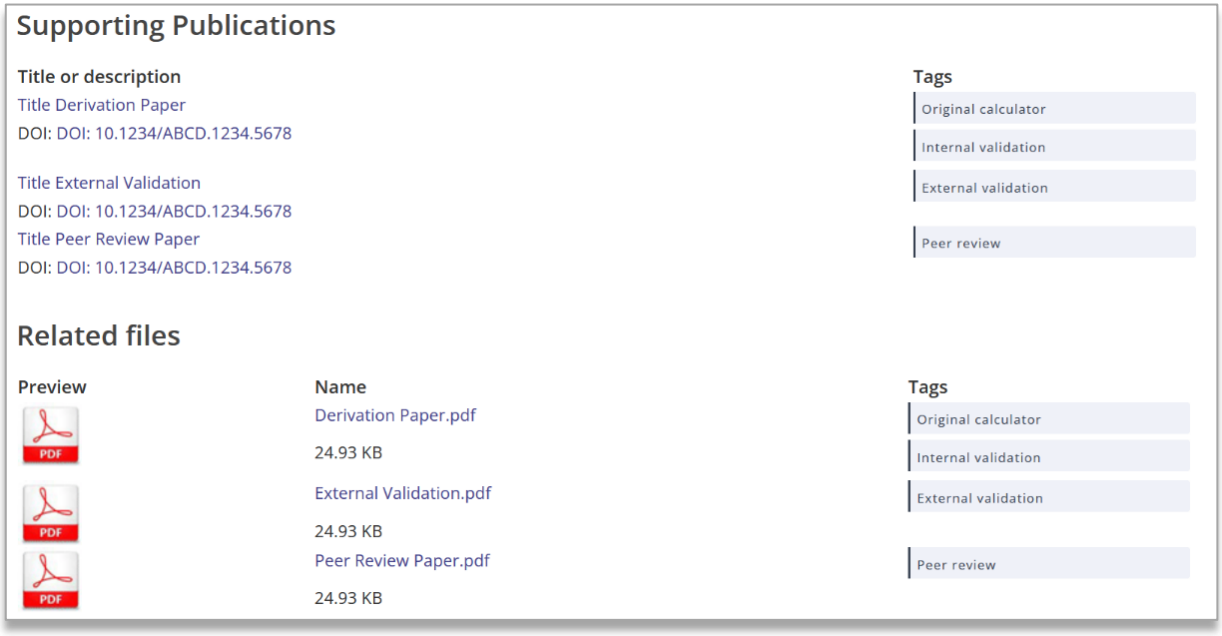

Figure 4. Example of the Supporting publication & Related files section under the Details tab.

H. Electronic label

The electronic label button opens a pop-up with the location and address of Evidencio, the LOT number, the UDI number, the CE-mark, the medical device logo and a download link for the declaration of conformity of the medical device. The example of the electronic label is shown in **Figure *5***.

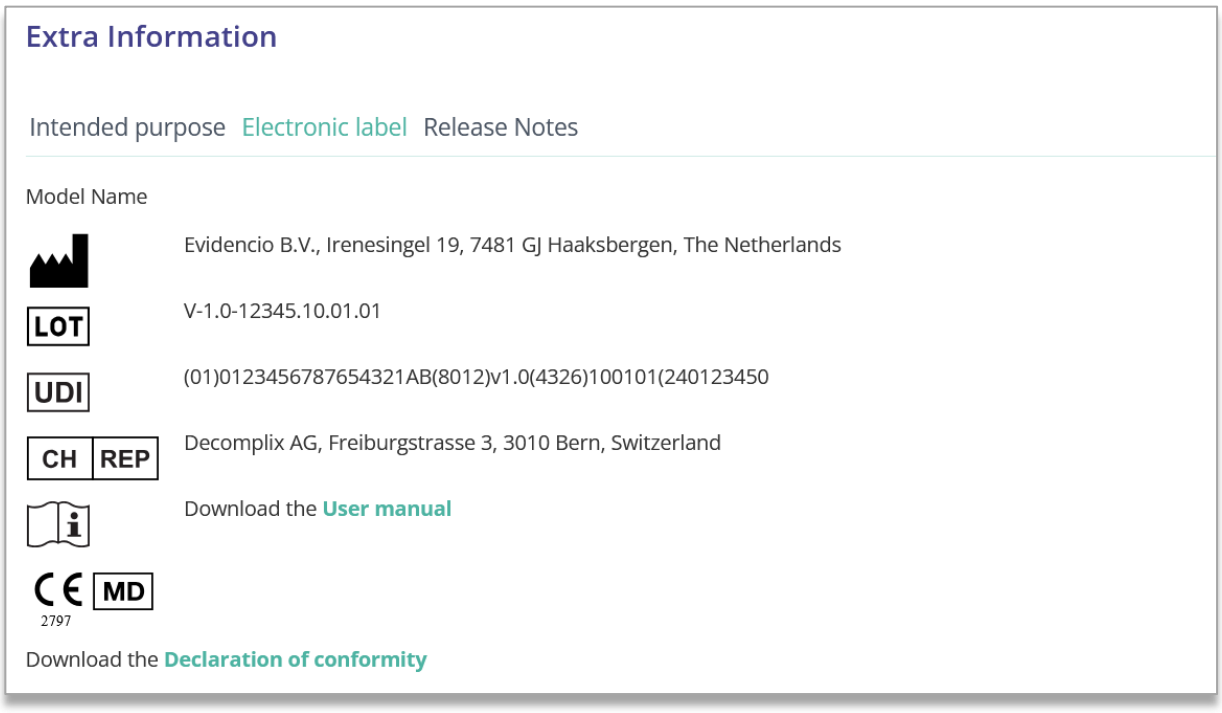

Figure 5. Example of an electronic label under the Electronic Label tab.

I. Intended purpose

Under this tab, the intended purpose can be found, containing a lot of information regarding the model, its user, target population, clinical benefit, etc. This information is also provided in this manual and can be found in **Chapter 6** on **page 5**.

J. Release notes

Under this tab the most recent release notes can be found, noting the most significant changes between the versions of the model found on the Evidencio website.

The 'Release Notes' button opens a pop-up with the latest release notes of the model. Here you can find a list of the most significant changes over the different versions of the model. Additionally, if there are any known residual anomalies the user should be aware of, they are listed here. It is recommended to read these notes after a version update to see if these changes are relevant to you.

K. User manual

This user manual can be found in three places: 1) under the short description of the model on the Evidencio model page, 2) on the right of the model page, and 3) as a tab in the electronic label screen. Additionally, all versions of the user manual can be found in the general page for all user manuals for medical devices. The page can be found under the 'About' drop-down menu button as shown in **Figure 6**. The user manual page is shown in **Figure 7**.

This version of the manual can be printed if required. If necessary, a paper version of the manual can be requested to be sent to you by mail. Evidencio's contact details are listed in **Chapter 11** of this user manual.

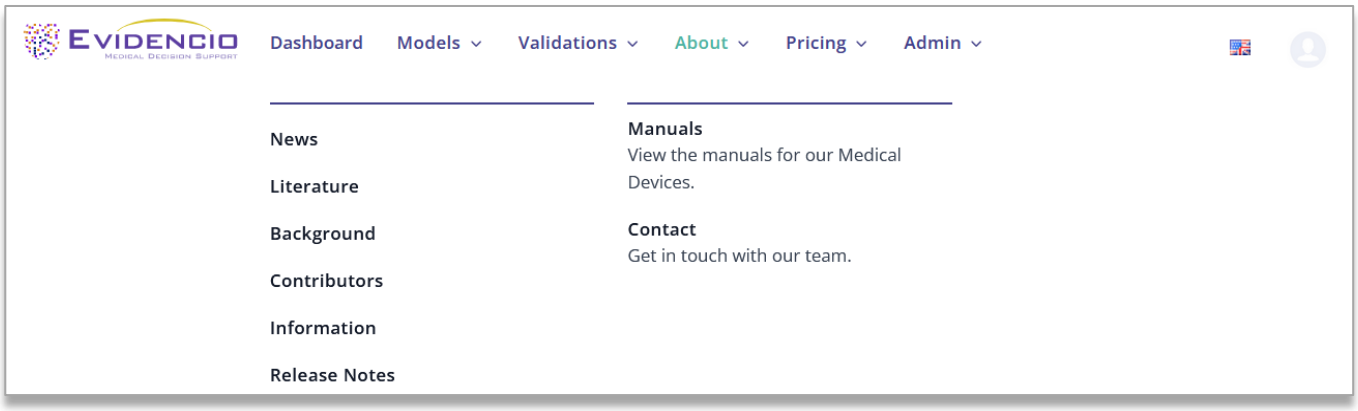

Figure 6. The drop-down menu where the user manual page can be found.

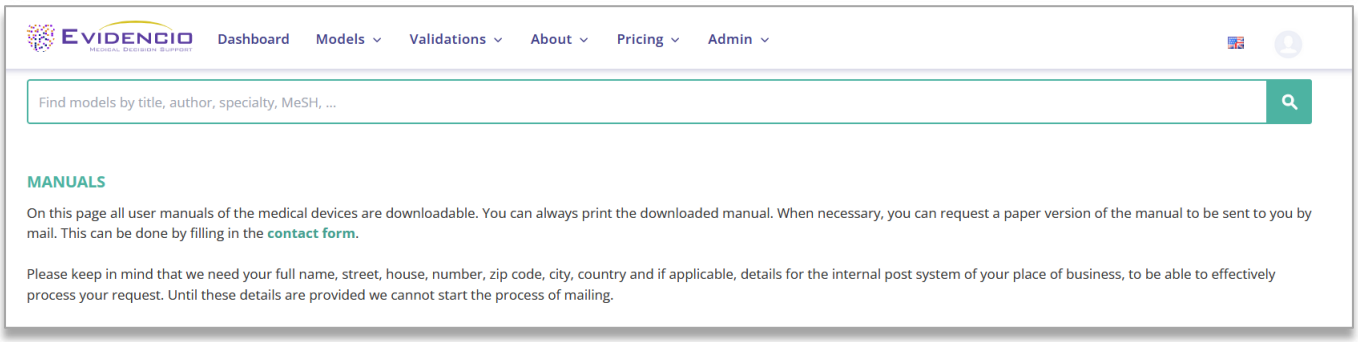

Figure 7. The user manual page for all user manuals.

L. Languages

The standard language on the Evidencio website is English. When other languages are available, these can be selected here. The list of languages may be different between models and may change when in time more languages will become available. Currently the Briganti Nomogram and its user manual are available in English.

Please note that, if a language is selected, only the user interface of the specific model will be translated, other general features and information on the site might still be set to one of our primary languages English, German, and Dutch.

When you find mistranslations, irregularities, or confusing or ambiguous use of language in English or any other language on the Evidencio website or in one of our manuals, please do not hesitate to contact us using the contact information provided at the end of this manual.

M. Input section

The Evidencio platform allows two separate input variables; categorical variables and continuous variables.

Categorical variables

In the example shown in shown in **Figure 8** and **Figure 9**, the example **Categorical Variable 1** concerns a categorical variable. The input that is wished to be used can be entered by clicking on either button. The selected button changes to green, as seen in **Figure 9**.

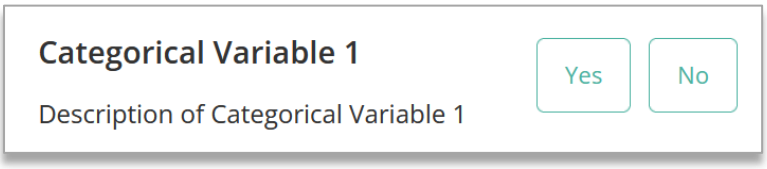

Figure 8. Example of a categorical variable, no button has been clicked and thus no input has been provided by the user.

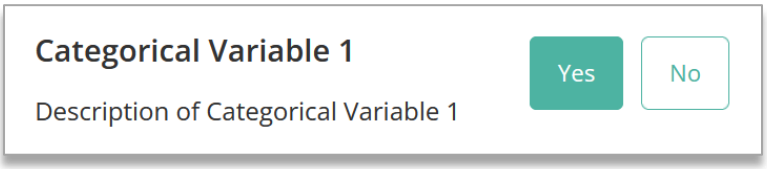

Figure 9. Example of a categorical variable, where the "Yes" button has been clicked.

Continuous variables

In the example shown in **Figure 10**, the **Continuous Variable 3**, exemplifies a continuous variable. The plausible ranges for which the model is tested and deemed valid are used.

The details for a patient can be entered by sliding the button to the correct value, or by entering the correct value in the box on the right-hand side (i.e., where the 10.2 mg/dL is entered for the **Continuous Variable 3**).

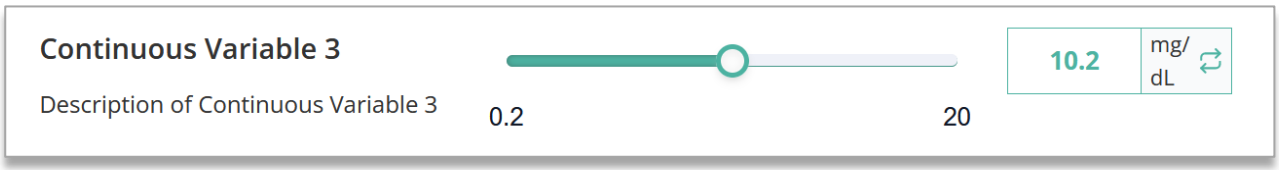

Figure 10. Example of a continuous variable, where "10.2 mg/dL" has been entered.

Unit conversion

Sometimes it is possible to use an unit conversion, by clicking on the unit when the green arrows are present. See **Figure 11** below where the unit has been clicked and switched.

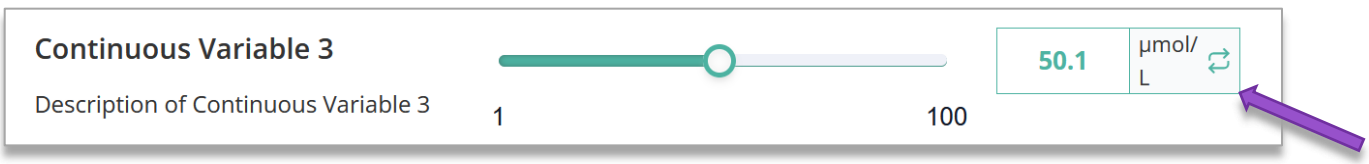

Figure 11. Example of a continuous variable where "50.1 $\mu mol/L$" has been entered.

Details on variable measurements

Directly underneath the name for each variable, additional details can be provided on the methods required to enter the correct value for each variable. Details may include but are not limited to; more detailed explanation of the variable, the ranges of the variables (for healthy individuals), or a description when a continuous variable should be true or false.

N. Result section

At the bottom of the page, the results of the model are shown.

Calculations alone should never dictate patient care, and are no substitute for professional judgement. See our full disclaimer on: https://www.evidencio.com/disclaimer.

Result calculation

When all variables are filled in, a result will be calculated. No risk is displayed until all variables are filled in and the result section will indicate; *"Set all parameters to calculate prediction."*

Result interpretation

In the result interpretation, a risk stratification is provided based on the risk score. Additional information about this stratification and the classification as found in the derivation and important validation cohorts may also be provided. An example of the information is shown in **Figure 12**.

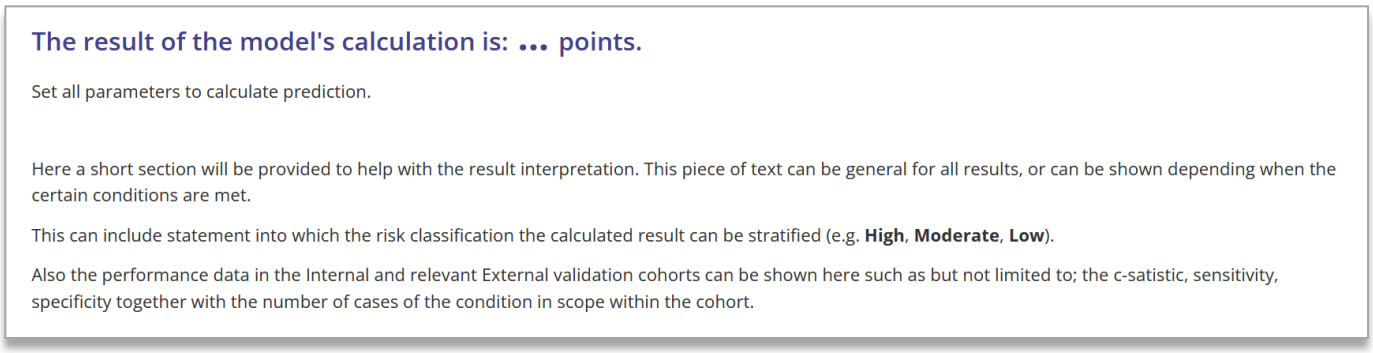

Figure 12. Example of the result display and information section.

O. Version / Model selection

Clicking on the Version tab allows the user to select a different version of the Briganti Nomogram for a list as displayed in **Figure 13**. Please note that the model currently selected is not presented in the dropdown menu.

Figure 13. Example of version selection tab.

11. Manufacturer details

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the country in which you, the reader, are established. A competent authority is the institute that governs all issues related to medical devices in a country.

Please contact Evidencio when you suspect any malfunction or changes in the performance of a medical device. Do not use the device, until Evidencio replies to your message that it is safe to start using it again.

Contact details of Evidencio:

Evidencio B.V., Irenesingel 19, 7481 GJ Haaksbergen, The Netherlands
www.evidencio.com
tel: +31 53 85195 08
e-mail: info@evidencio.com