DELIVERABLE

Project Acronym: **VALIDATE**

Grant Agreement number: **101057263**

Project Title: **Validation of a Trustworthy AI-based Clinical Decision Support System for Improving Patient Outcome in Acute Stroke Treatment**

D4.2 – Electronic patient recorded outcome framework (NORA) adaptation

Revision: 1.0

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Dissemination Level		
PU	Public, fully open	xxx
CO	Confidential, restricted under conditions set out in Model Grant Agreement	
CI	Classified, information as referred to in Commission Decision 2001/844/EC	

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Revision History, Status, Abstract, Keywords, Statement of Originality

Revision History

Revision	Date	Author	Organisation	Description
Set up	3july2023	Victoria Sala	VHIR	Structuring and content
First revision	24july2023	Marta Rubiera	VHIR	Review of sections
review	27sept2023	Victoria Sala	VHIR	Adding guidelines
Final doc	30oct2023	Marta Rubiera	VHIR	Final Review

Date of delivery	Contractual:	31.10.2023	Actual:	31.10.2023
Status	final ☒ /draft ☐			

Abstract (for dissemination)	This document presents a summary of how prospective data will be collected for Validate and in which type of data electronic medical records (NORA) they will be treated, as well as a guide on how these variables will be collected.
Keywords	eCRF, NORA, Variables

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation, or both.

Table of Content

1 NORA

NORA is an innovative nudging-based digital platform for professionals and a holistic app for patients that provides health education to patients and allows continuous communication between patients and healthcare providers through chats and/or video calls. It also allows the recollection of PROMs through survey administration to patients. The technological solution NORA, developed and implemented at Hospital Universitari Vall d'hebron-VHIR, is an evidence-based tool that provides a holistic approach for improving vascular risk factor control (informative videos, specific diets, physical activity measurement), and treatment adherence, promoting behavioral changes towards healthy lifestyle (nudging) and enhancing patient engagement (alarms for treatment compliance and chat/video-calls between patients and health care providers). NORA will capture PROMS at baseline, 7-day, 1 month and 3 months after stroke. NORA integration is already implemented in the Hospital Vall d'hebron-VHIR, and it will be performed in the other clinical partners involving clinicians, IT departments and patients/caregivers, thanks to NORA.

The patient follow-up functionality is based on NORA technology, which has shown to increase the Patient Reported Outcomes (PROs) recollection rate from 43% to 89%, increase the rate of treatment adherence by 45%, and improve vascular risk factors control from 34% to 76%. NORA app provides individualized information of stroke treatment, vascular risk factor control (with informative videos, specific diets, physical activity measurement), alarms for treatment compliance and chat/video-calls between patients and healthcare providers. It also has the possibility to provide tele-occupational therapy, guided by rehabilitation physicians, to promote return to previous activities or adaptation to disabilities after hospital discharge.

NORA additionally provides a data visualization framework for healthcare professionals, with remote homecare functionalities for patients and caregivers, adopting an already designed holistic web-platform and smartphone app technology by NORA. The platform will provide a fully inclusive and comprehensive information package, with structured symptom management, personalized information, data visualization and communication between patients and healthcare professionals.

For the VALIDATE prospective observational shadowing study, an electronic case report form (eCRF) is created within the NORA platform. Three similar databases will also be created in the NORA platform, allocated in safe servers of each of the clinical centers, with information from the eCRF, patient prediction (CSV table from laptop in CT suite) and automatic transfer of PROMs from the NORA app (see list of variables in the hyperacute phase).

In the data collection of the project, we will have two parts. On one hand we will have the data from the demonstrator (App) that will be transferred from the App to NORA by a CSV table from laptop in CT suite. On the other hand, we will have additional data that will be collected during the patient's stay in the hospital and it will be entered manually in NORA. Later on, the prospective patient data (PROMS) will be collected through NORA. If the patient is not using NORA for PROMs recollection, the PROMs will be manually filled by a researcher through the eCRF. The access for the professional will be a personal user identificator and a password. In addition, for the access of patients to the NORA app, also a personal ID and password is required. A NORA's user manual for patients (app) and professionals (web platform front-end) will be shared and available with the sites.

2 Variables

2.1 List of variables to be recollected in the hyperacute stroke phase by the app

The shadow researcher will recollect the following variables and these will also be collected in a database allocated in NORA IN each of the clinical centers, and filled through an eCRF after the acute phase: (* notes the minimal set of mandatory variables for prediction)

Clinical data acquisition	Age*
	Biological sex*
	NIHSS
	Systolic blood pressure
	pre-stroke mRS*
	oral anticoagulant
	serum glucose
	Hypertension
	Hypercholesterolemia
	Ischemic heart disease
	Smoking
	Valvular heart disease
	Previous Stroke
	Atrial Fibrillation
	Diabetes mellitus
	Onset time
	Admission time
Neuroimaging data acquisition	Imaging time
	ASPECTS
	Location of occlusion
	Tandem occlusion
	Collateral score (CTA)
	IVT
	IVT time

2.2 eCRF variables (If some of the previous are not available from the hyperacute phase, they will be manually filled by the research team through the eCRF)

- Date of informed consent formulary (ICF) signature

- Version of ICF signature
- Gender: Female/Male/Transgender male/Transgender female/Gender variant: non-conforming/Prefer not to say
- Ethnicity: Asian/ Black /Hispanic or Latino/White/ Other / Unknown
- Thrombectomy: yes/no
- Time of arterial puncture for EVT
- Intracranial occlusion location (Digital subtraction angiography): No/ Yes: TICA, M1, M2, A1, A2, P1, P2, VA, BA, distal occlusion
- Baseline TICI (0, 1, 2a, 2b, 2c, 3)
- TICI after first pass thrombectomy
- Final TICI
- Time of recanalization/end of procedure (if no recanalization)
- Complications during thrombectomy: No / Yes: distal embolization, dissection, acute hemorrhage, severe vasospasm (requires treatment)
- Hemorrhagic transformation (ICH): Yes/no
- SICH: Yes/no
- NIHSS 24h
- In-hospital complications: No / Yes: pneumonia, other infections, congestive heart failure, acute coronary event
- NIHSS 5 days or Discharge
- mRs 5 days or Discharge
- In-hospital mortality: yes/no
- mRs 90 days

2.3 Case-by-case user feedback for usability and evaluation (To collect feedback on the usage of the app) by the research team through the eCRF)

Usability
Addressee: shadow researcher
Questions:

- Was the use of the tool seamless in terms of data input, prediction and feature impact assessment? (rate from 0 to 5)
- Was the use of the tool seamless in terms of time and responsiveness? (rate from 0 to 5)
- Was the prediction of the model clearly visualized? (rate from 0 to 5)
- Was the confidence of the model clearly visualized? (rate from 0 to 5)
- Were the feature impacts clearly visualized? (rate from 0 to 5)

Performance
Addressee: shadow researcher
Questions:

- Do you think the tool provided additional information or insights into the given stroke case? (rate from 0 to 5)
- Do you think prediction of the likely outcome was important and informative in the given stroke case? (rate from 0 to 5)
- From the explanation (feature impact), I know how the algorithm makes its predictions (yes/no)

- This explanation (feature impact, confidence level) of how the algorithm works is satisfying (yes/no)
- This explanation (feature impact, confidence level) of how the algorithm works has sufficient detail (yes/no)
- This explanation (feature impact, confidence level) of how the algorithm works seems complete (yes/no)
- This explanation (feature impact, confidence level) of how the algorithm works tells me how to use it (yes/no)
- This explanation (feature impact, confidence level) of how the algorithm works is useful to my goals (yes/no)
- This explanation (feature impact, confidence level) of the algorithm shows me how accurate its predictions are (yes/no)

2.4 NORA: Patient reported outcomes measures (PROMs) (or manual filling in eCRF for no-users of NORA)

- HADS_SCORE_DEPRESSION_90 days (0 to 21)
- HADS_SCORE_ANXIETY_90 days (0 to 21)
- PROMIS10_PHYSICAL_ 7 days (0 to 20)
- PROMIS10_MENTAL_7 days (0 to 20)
- PROMIS10_PHYSICAL_90 days (0 to 20)
- PROMIS10_MENTAL_90 days (0 to 20)
- VAS_EQ5D_7 days (0-100)
- VAS_ EQ5D_90 days (0-100)

3. eCRF COMPLETION GUIDELINES FOR VALIDATE via NORA

General indications:

− Complete all required fields on the screens. Ensure all entries are in English and are accurate, consistent, complete, and medically logical. Avoid using abbreviations and symbols wherever possible.

− Data should be entered as soon as possible; evaluation or assessment and queries should be answered as soon as possible, unless otherwise communicated by the team.

− Ensure there are no missing data (blank fields) in the Electronic Case Report Form (eCRF). Where requested to 'specify' for an item in the eCRF, ensure that a specific entry is made.

– Forms with data should not be inactivated by sites. Only forms without data should be inactivated by sites. This should only occur in rare cases.

− Visit dates should be complete and chronological according to the protocol. All date fields are entered as Day/Month/Year and HH:MM.

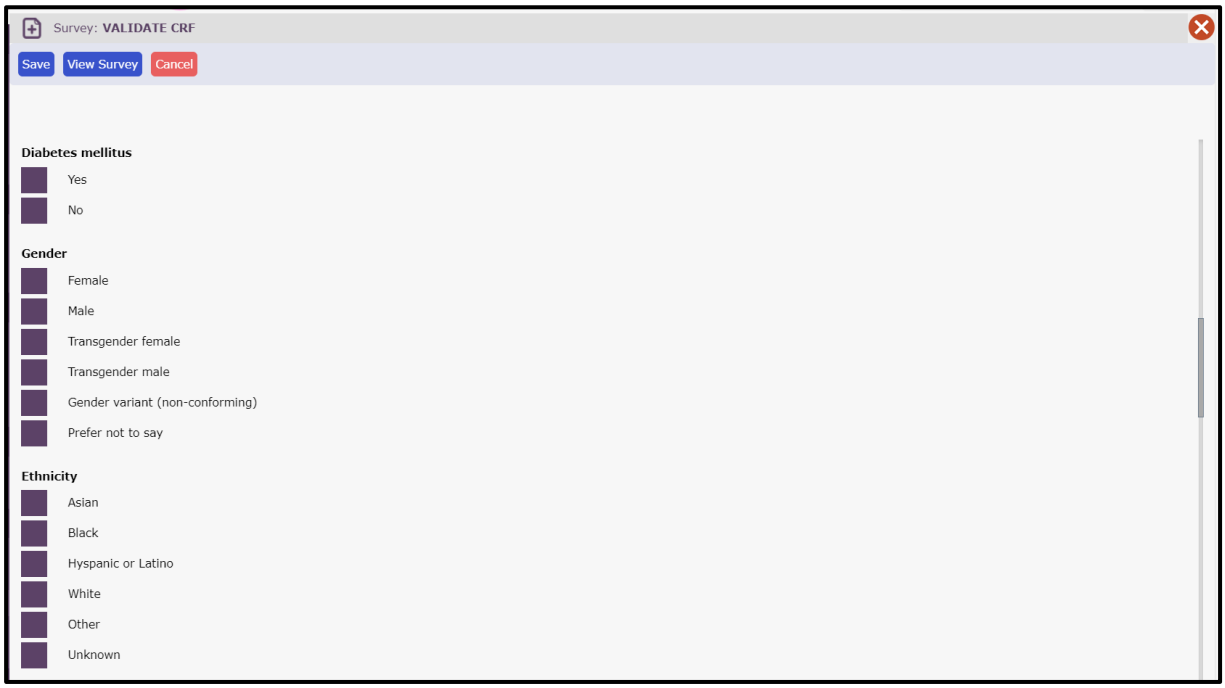
− There are 3 different types of entering/answering data:

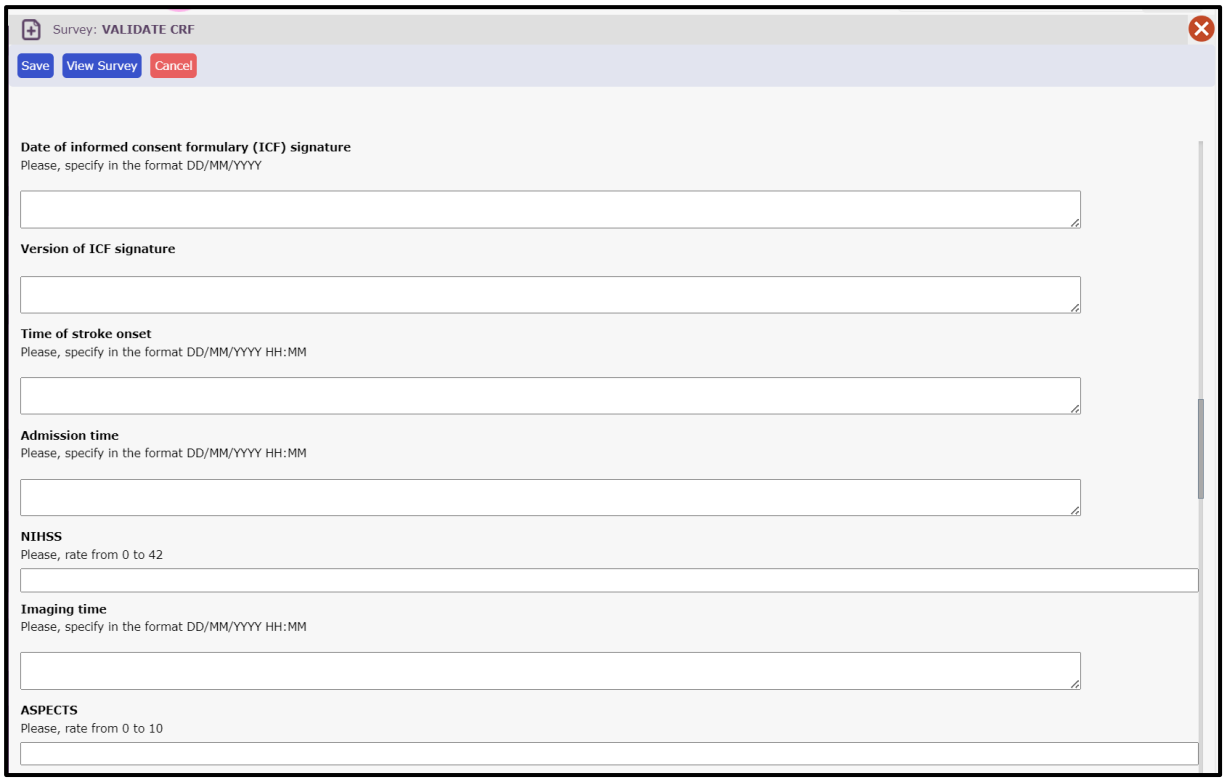
- Questions with a numeric answer
- Questions with dichotomic answer
- Questions with rate from 0 to 5 (being 0 strongly disagree and 5 totally agree)

-It will be possible to save the data and leave some of them blank, to be able to enter it later once you have the data. It will also be possible to edit the data.

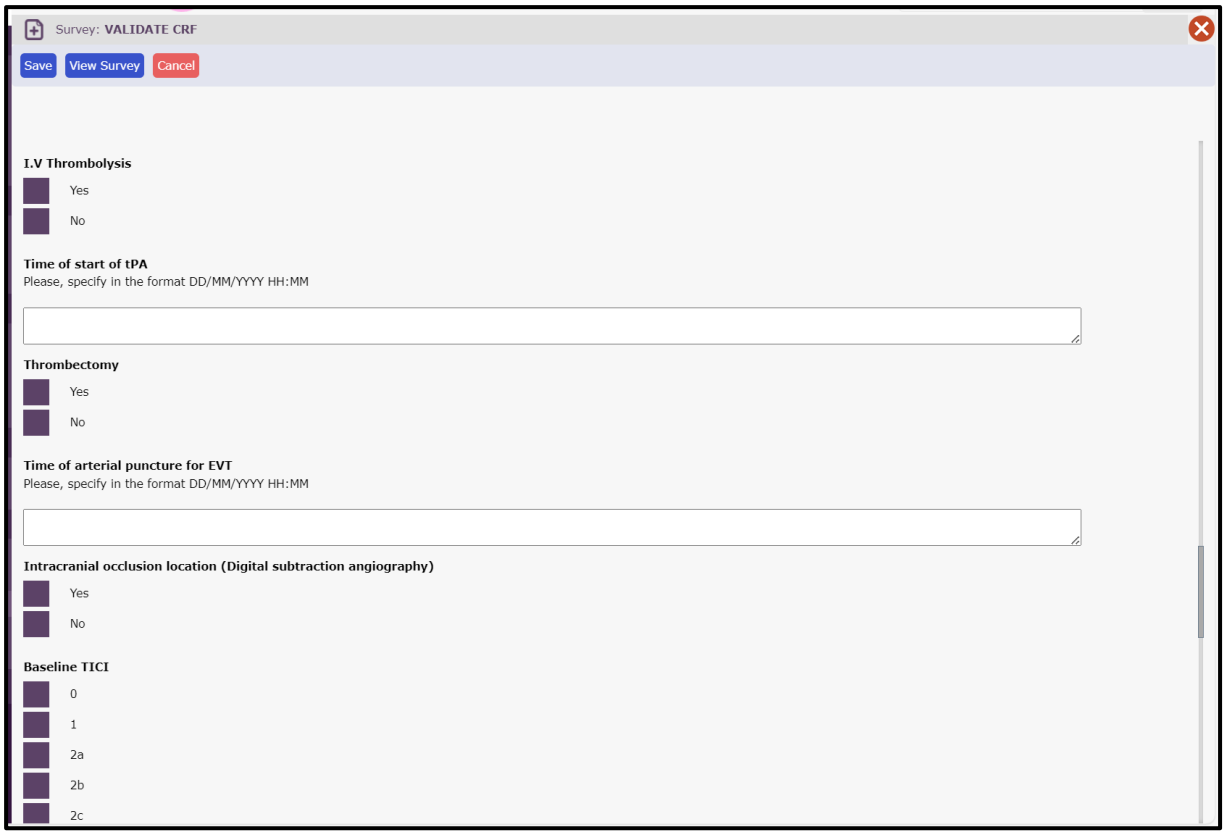
Below are images of how the validate eCRF will be displayed:


Survey: VALIDATE CRF
Save
View Survey
Cancel
Hypercolesterolemia
Yes
No
Ischemic heart disease
Yes
No
Smoking
Yes
No
Valvular heart disease
Yes
No
Previous stroke
Yes
No
Atrial Fibrillation
Yes
No

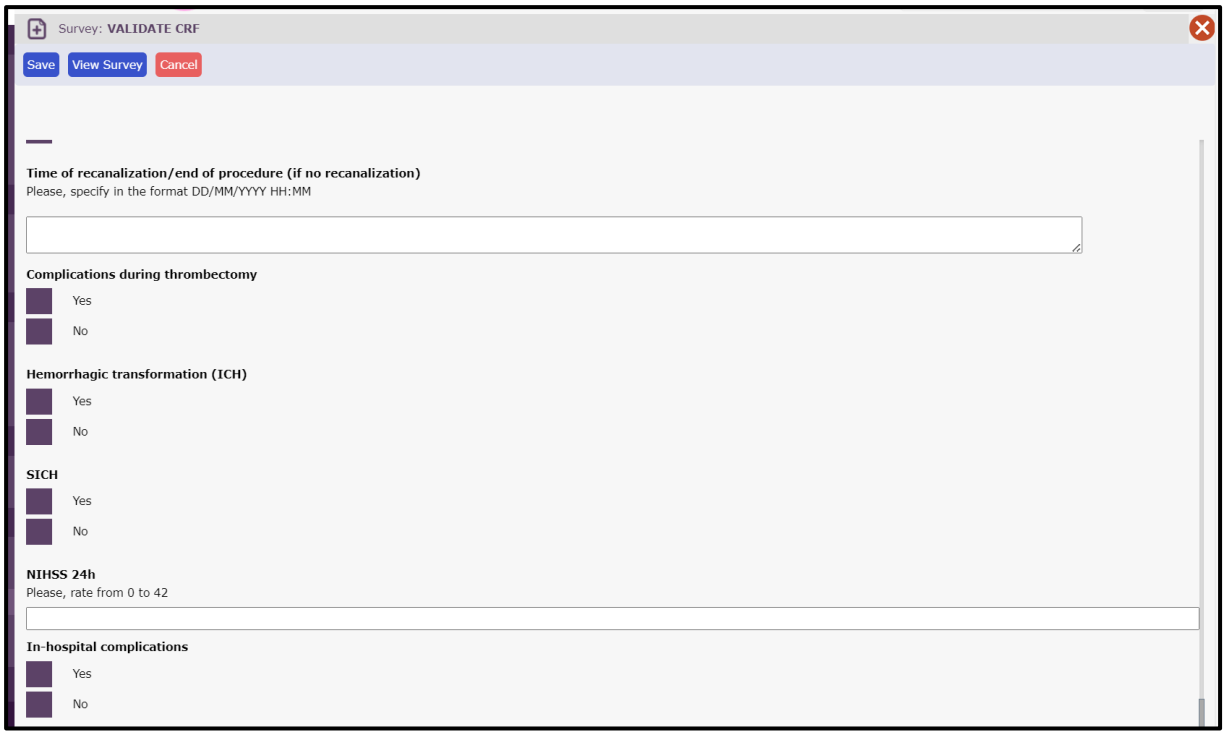

Survey: VALIDATE CRF
Save
View Survey
Cancel
Diabetes mellitus
Yes
No
Gender
Female
Male
Transgender female
Transgender male
Gender variant (non-conforming)
Prefer not to say
Ethnicity
Asian
Black
Hyspanic or Latino
White
Other
Unknown


Survey: VALIDATE CRF
Save
View Survey
Cancel
Date of informed consent formulary (ICF) signature
Please, specify in the format DD/MM/YYYY
Version of ICF signature
Time of stroke onset
Please, specify in the format DD/MM/YYYY HH:MM
Admission time
Please, specify in the format DD/MM/YYYY HH:MM
NIHSS
Please, rate from 0 to 42
Imaging time
Please, specify in the format DD/MM/YYYY HH:MM
ASPECTS
Please, rate from 0 to 10

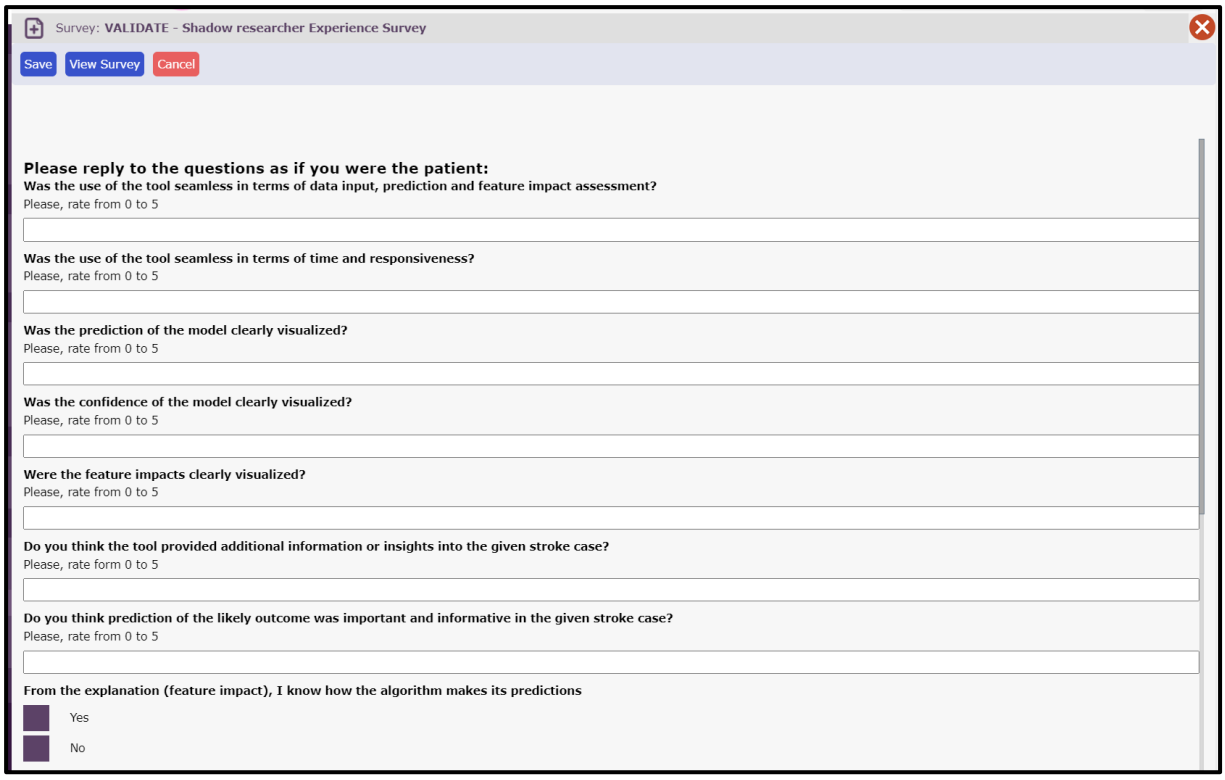

Survey: VALIDATE CRF
Save
View Survey
Cancel
Intracranial occlusion location (CT angiography)
Yes
No
Intracranial occlusion location (CT angiography) - Yes
Answer only if an Intracranial Occlusion Location (CT Angiography) is performed
TICA
M1
M2
A1
A2
P1
P2
VA
BA
Distal occlusion
Collateral score (CTA)
Please, rate from 0 to 3
Tandem occlusion
Yes
No


Survey: VALIDATE CRF
Save
View Survey
Cancel
I.V Thrombolysis
Yes
No
Time of start of tPA
Please, specify in the format DD/MM/YYYY HH:MM
Thrombectomy
Yes
No
Time of arterial puncture for EVT
Please, specify in the format DD/MM/YYYY HH:MM
Intracranial occlusion location (Digital subtraction angiography)
Yes
No
Baseline TICI
0
1
2a
2b
2c


Survey: VALIDATE CRF
Save
View Survey
Cancel
Baseline TICI
0
1
2a
2b
2c
3
TICI after first pass thrombectomy
0
1
2a
2b
2c
3
Final TICI
0
1
2a
2b
2c
3


Survey: VALIDATE CRF
Save
View Survey
Cancel
Time of recanalization/end of procedure (if no recanalization)
Please, specify in the format DD/MM/YYYY HH:MM
Complications during thrombectomy
Yes
No
Hemorrhagic transformation (ICH)
Yes
No
SICH
Yes
No
NIHSS 24h
Please, rate from 0 to 42
In-hospital complications
Yes
No


NIHSS 5 days or Discharge
Please, rate from 0 to 42
mRs 5 days or Discharge
Please, rate from 0 to 5
In-hospital mortality
Yes
No
mRs 90 days
Please, rate from 0 to 5


Survey: VALIDATE - Shadow researcher Experience Survey
Save
View Survey
Cancel
Please reply to the questions as if you were the patient:
Was the use of the tool seamless in terms of data input, prediction and feature impact assessment?
Please, rate from 0 to 5
Was the use of the tool seamless in terms of time and responsiveness?
Please, rate from 0 to 5
Was the prediction of the model clearly visualized?
Please, rate from 0 to 5
Was the confidence of the model clearly visualized?
Please, rate from 0 to 5
Were the feature impacts clearly visualized?
Please, rate from 0 to 5
Do you think the tool provided additional information or insights into the given stroke case?
Please, rate form 0 to 5
Do you think prediction of the likely outcome was important and informative in the given stroke case?
Please, rate from 0 to 5
From the explanation (feature impact), I know how the algorithm makes its predictions
Yes
No


Survey: VALIDATE - Shadow researcher Experience Survey
Save
View Survey
Cancel
Yes
No
This explanation (feature impact, confidence level) of how the algorithm works is satisfying
Yes
No
This explanation (feature impact, confidence level) of how the algorithm works has sufficient detail
Yes
No
This explanation (feature impact, confidence level) of how the algorithm works seems complete
Yes
No
This explanation (feature impact, confidence level) of how the algorithm works tells me how to use it
Yes
No
This explanation (feature impact, confidence level) of how the algorithm works is useful to my goals
Yes
No
This explanation (feature impact, confidence level) of the algorithm shows me how accurate its predictions are
Yes
No