

Everything is same as in the document PK-KIT v1.0 except the changes requested by Poland which are given below:

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[Changes on DASHBOARD](#)

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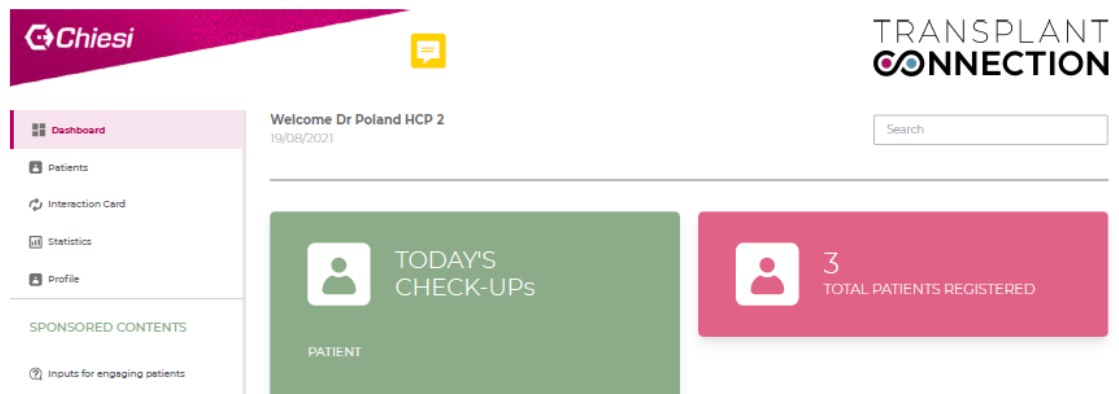
[Changes on Statistics](#)

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[Changes on Ticket Section](#)

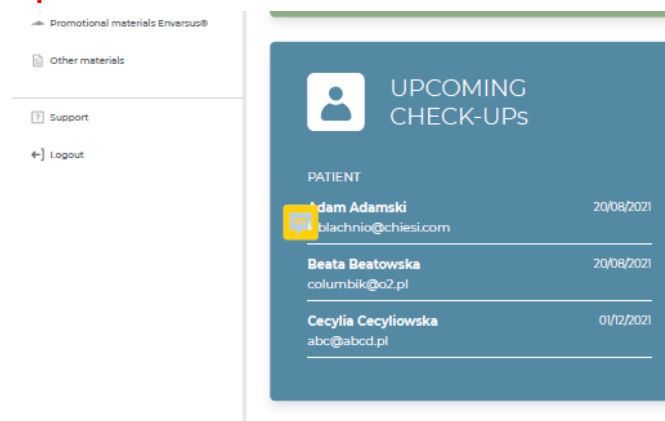
## Changes on DASHBOARD

1. In the Dashboard Tab We need to add a disclaimer above the name of the HCP.  
Lines will be (**EN: All patient data are secured and encrypted. Chiesi has no access to any data of your patients. PL: Wszystkie wprowadzone dane pacjentów są zabezpieczone i szyfrowane. Chiesi nie ma dostępu do danych Twoich pacjentów.** )



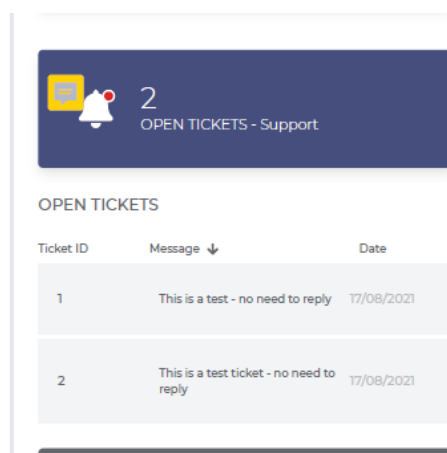
a.

2. In the Dashboard tab, **Maximum limit of listing in the Next Check - Up section should be upto 10.**



a.

3. We need to hide this Open Ticket section from Dashboard, & **Tickets generated by HCP will be visible to Affiliate only and it depends on him whether he wants to give access to Technical Admin or not.**



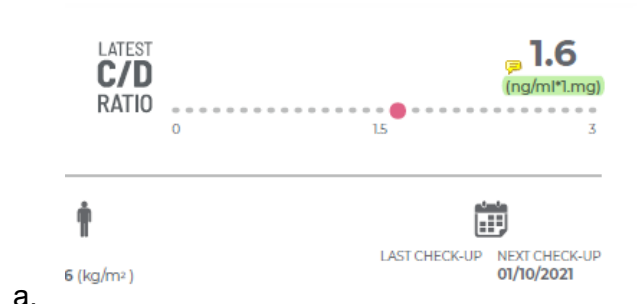
a.

4. Footers of the page should have these things in them.
  - a. The footer of each page should include links of additional tabs to the formal dokumenta:
  - b. - Terms of use (final version will be provided later)
  - c. - Privacy Policy (final version will be provided later)
  - d. - Patients Consent Form do download/print (will be provided later)
  - e. - Chiesi address and contact details as the owner of this platform (TBD. CHIESI Global or Chiesi PL?)
  - f. - link to the subpage when phs can find the instruction of advers events reporting with heading (PL): Zgłoś działanie niepożądane leku
  - g. and at the very bottom:
  - h. - date of last update (PL): Data aktualizacji: \_\_/\_\_/\_\_\_\_ r.)
  - i. - the local reference number: CHIESI/KBŁ/ENV/95/09/2021



## Changes on PATIENTS TAB

1. In patients listing, we need to change the unit. It should be **(ng/ml\*1/mg)**



- a.
2. Information in this info cloud should be in **Polish Language.**

 BMI  
 25.56 (kg/m<sup>2</sup>)

 LAST CHECK-UP  
 NEXT CHECK-UP  
 01/10/2021

SYMPTOMS  


- 1 Sleep Disorders
- 1 High Blood Pressure
- 3 Tremors

a.

3. We need to display the brand name in the prescribed medicine section. It should be like **Tacrolimus Daily Total Dose: 3,75 mg (BRAND NAME)**

AGE  
 55 yrs

TRANSPLANT DATE  
 15/08/2018

PRESCRIBED THERAPY 


Tacrolimus Daily Total Dose: 3.75 mg

---

CELLCEPT  
 Encorton

a.

4. While adding a new patient, we need to give **multiple choices** in the Transplanted organ. He will be able to select both Kidney and Liver.

 Transplanted Organ

☐ Kidney  
☐ Liver  
☒ Other

Pluca

a.

5. If two organs are transplanted, we will ask **2 dates of Transplantation**

**\*Date of Transplantation**

15/08/2017

a.

6. We need to **hide the Ethnicity and Genotype section** while adding patients.

**Ethnicity**

☐ White

☐ Black

☐ Asian

☐ Hispanic

☐ Other

Specify

**Genotype**

☐ CYP3A5\*1/\*1

☐ CYP3A5\*1/\*3

☐ CYP3A5\*3/\*3

☐ Other

Specify

NEXT

a.

7. Height and Weight fields should be integers and have limits.

a. **Height range: 50 - 220 cm**

b. **Weight range; 30 - 300kg**

**\*Height:**

(cm)

123738403.333333

**\*Weight:**

(kg)

233304.2222

c.

8. Email should not be mandatory. **We will generate one time unique Alphanumeric key for each patient.**

**\*Email:**

dariusz@email.com

a.

9. While adding a patient, in the prescribed therapy section we need to make these 2 changes.

- In daily doses, we need to use a comma instead of a dot. It should be 3,75 rather than 3.75.
- Time should be in 24 hour format instead of AM and PM

**Prescribed Therapy**

TACOROLIMUS

Brand:

Substance:

POSLOGY

OD 24 hours ☒ BID 12 hours ☐

Total Daily Dose (mg):

Time 1:

Time 2:

c.

10. In the other drugs section, we need to change these 2 things.

- We need to show a text field in sequence with Substances, with the name Posology. HCP will be able to write some text here.
- In substances dropdown.
  - They should be arranged in alphabetical order.
  - They should be in Polish.

**OTHER DRUGS**

ADD

Brand: <input type="text" value="CELLCEPT"/>	Substance: <input type="text" value="Mycophenolate mofetil"/>	
Brand: <input type="text" value="Encorton"/>	Substance: <input type="text" value="Prednisone"/>	
Brand: <input type="text"/>	Substance: <input type="text" value="Select"/>	

BACK NEXT

c.

11. In patient's summary section:

- Email should be in small alphabets.
- It should be cm not Cm.
- It should be kg not Kg.
- It should be kg/m^2 not Kg/m^2

Date of birth: 01/08/1966

Email:

Height: 178 Cm

Weight: 81 Kg

BMI: 25.56 (Kg/M<sup>2</sup>)

e.

12. Date in 24 hour format here too.

MEDICAL INFORMATION

Transplanted Organ: Kidney  
Date of Transplantation: 15/08/2018

PRESCRIBED THERAPY

Envarsus      Total Daily Dose: 3.75 mg      Interval: 24 hrs      Time: 8:30 AM

CELLCEPT  
Encorton

BACK      SAVE

a.

13. In the General Information section, we need to resolve this.

- a. There should be space between 178 and cm. It's 178cm right now.
- b. 81Kg should be written as 81 kg.

GENERAL INFORMATION

Adam Adamski

Date of birth: 01/08/1966  
Height: 178cm  
Weight: 81Kg

Allergies

c.

14. Next check should be rephrased:

- a. It should be rephrased as "Upcoming Check-Up".
- b. This feature should be included in the Patient's app.
- c. It should take feedback from the patient. (Not sure. )

penicylina

Note

To jest pacjent testowy

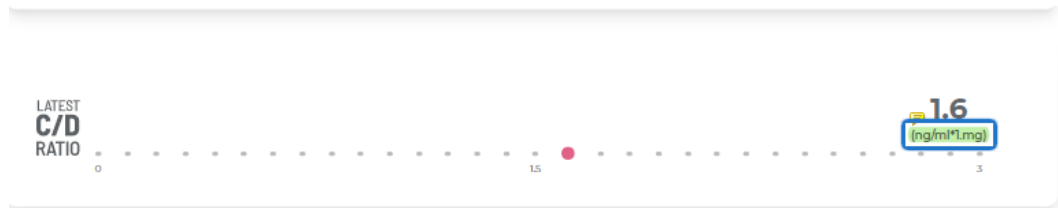
Next Check-Up

01/10/2021

d.

15. Wrong notation.

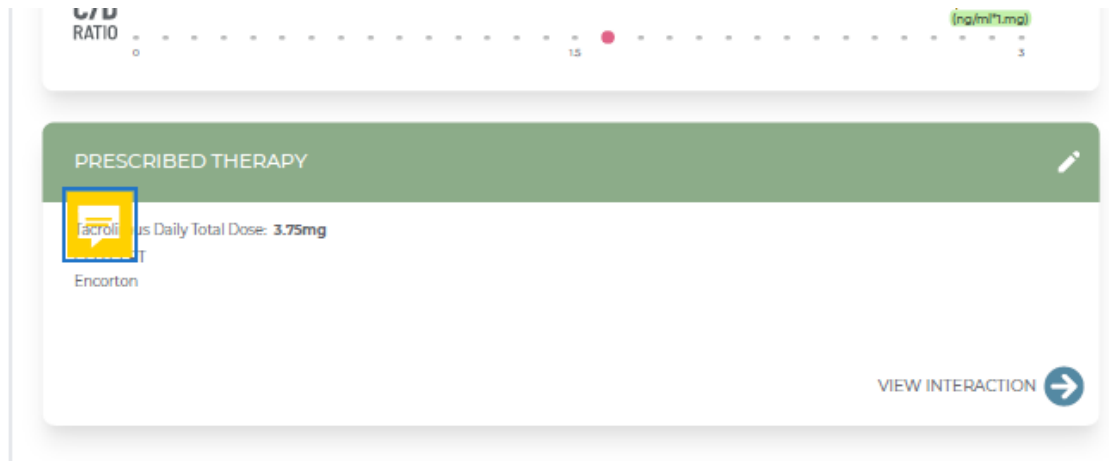
- a. It should be (ng/ml\*1/mg)



b.

16. Add brand name.

a. It should be like **Tacrolimus Daily Total Dose: 3,75 mg (BRAND NAME)**



b.

17. Need to show this graph in a different format.

a. **Not sure. How to display?**



b.

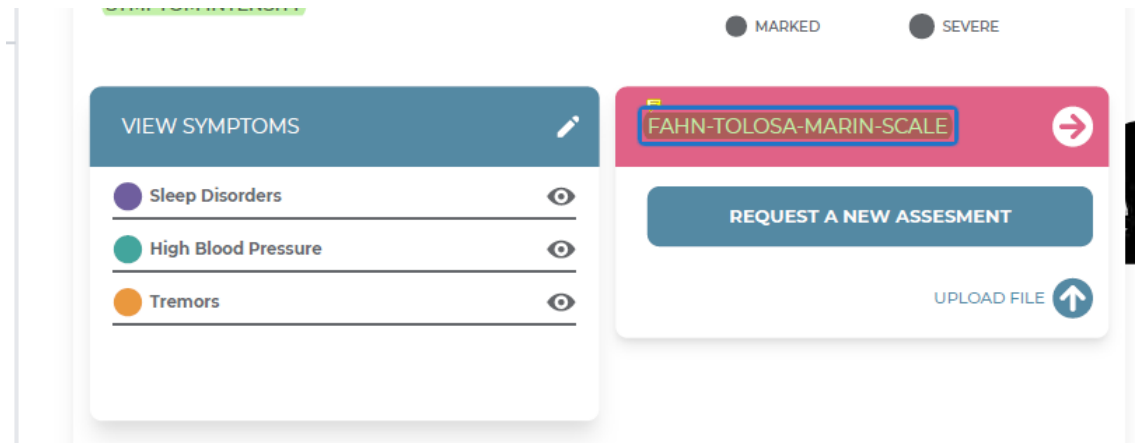
18. Change heading name.

a. We can't use this name, because we don't use full FTM scale - it is only one part of FTM Scale

b. **Please change this heading for (PL):**

c. **OCENA NASILENIA DRŻENIA RĄK**

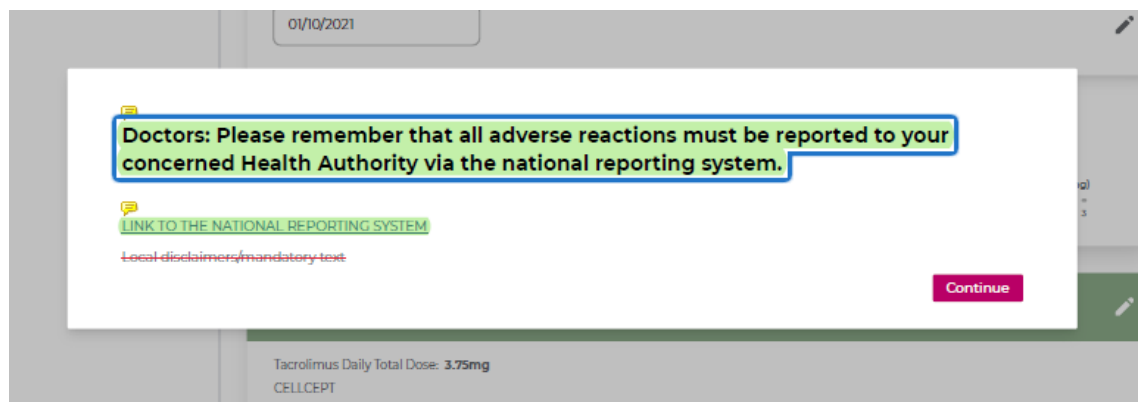




d.

#### 19. Changes in Pop-Up.

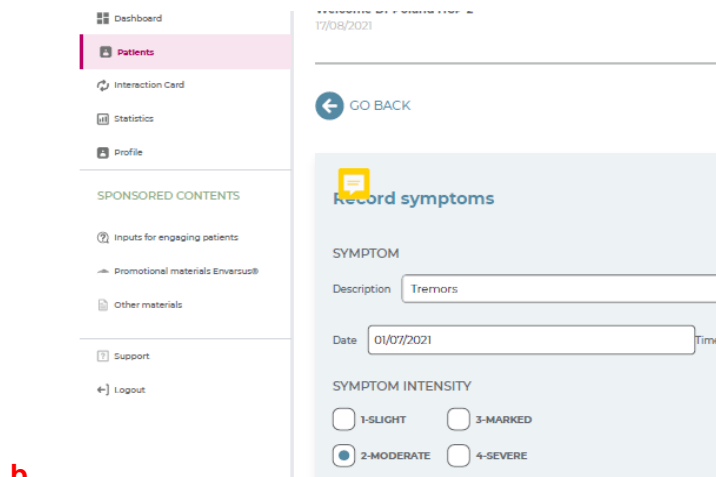
- Change heading text to : **UWAGA: wszelkie działania niepożądane leków należy zgłosić do Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych lub do odpowiedniego podmiotu odpowiedzialnego.**
- Change Link to: **LINK DO KRAJOWEGO SYSTEMU ZGŁOSZEŃ**  
{<http://urpl.gov.pl/pl/produkty-lecznicze/monitorowanie-bezpiecze%C5%84stwa-lek%C3%B3w/zg%C5%82o%C5%9B-dzia%C5%82anie-niepo%C5%BC%C4%85dane-0>}
- Need to delete the last line. (Mandatory text line)
- .



e.

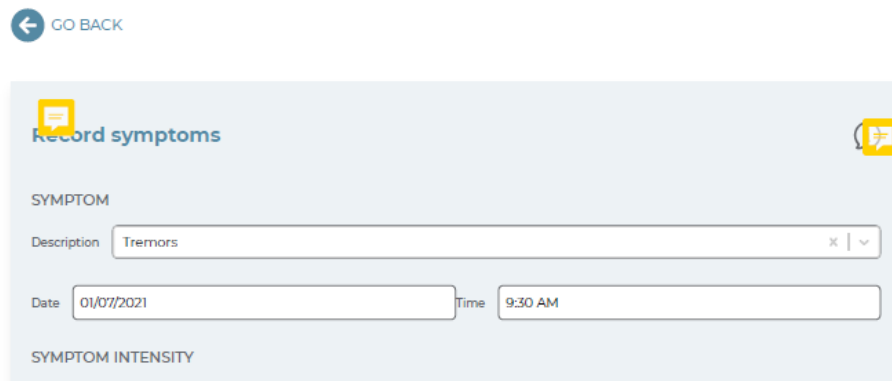
#### 20. We need to change this section.

- Not sure what to do.**



b.

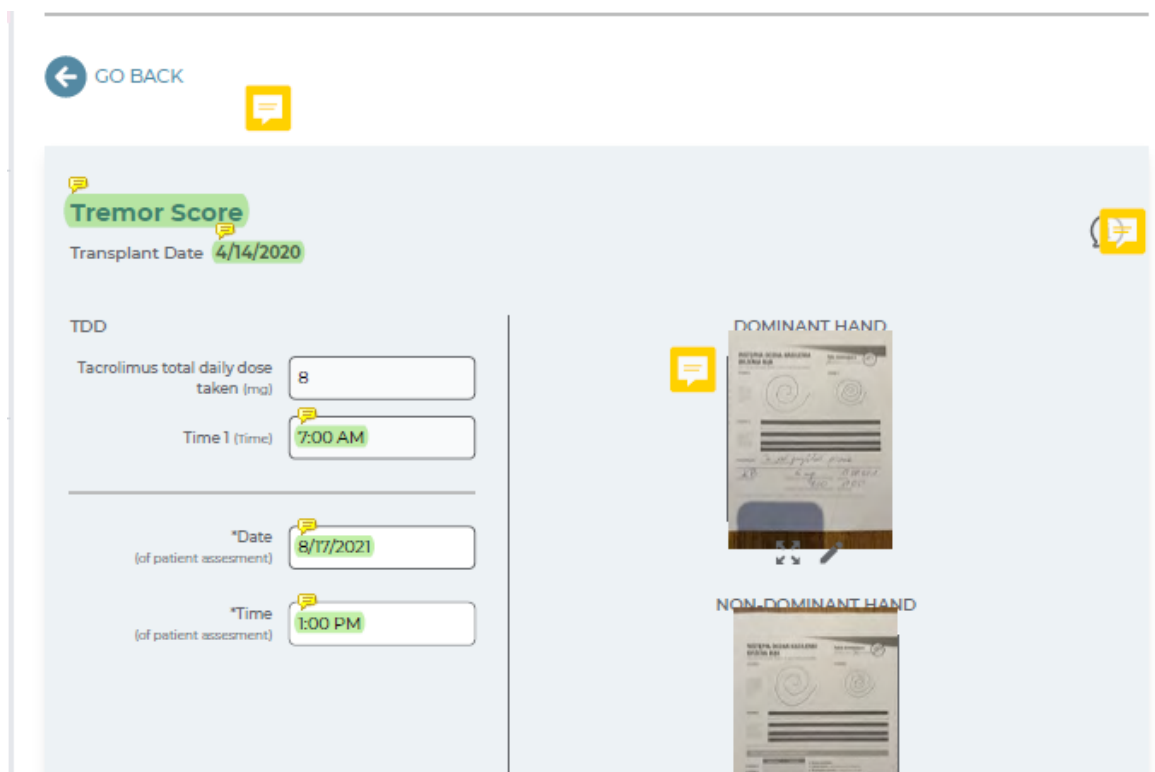
21. Information cloud is not active.



a.

22. On the FTM scale section.

- We need to show a note that **the tool is only a certain domain of FTM scale, not a complete assessment.**
- Cloud is not active.
- Tremor score should be changed to **Wstępna ocena nasilenia drżenia rąk**
- wrong order of the date, **should be: DD/MM/YYYY**
- Time should be in **24 hour format.**
- We need to give features **to allow them to upload these photos directly from their mobile device.**



g.

23. Make these changes.

- We can't use this name, because we don't use the full FTM scale - it is only one part of FTM Scale. **Please change this heading for (PL): OCENA NASILENIA DRŻENIA RĄK**
- wrong order of the date, should be: DD/MM/YYYY**
- Time should be in **24 hour format.**
- For Tremor Score which is shown as **(6-Slight)**

i. We will show the score and agenda below. (Poland only)

e. .

TEST	DATE OF ASSESSMENT	TIME OF ASSESSMENT	TREMOR SCORE
Fahh-Tolosa Marin Scale Uploaded 8/17/2021	8/17/2021	1:00 PM	6-SLIGHT

f.

24. In Distribution of Tacrolimus or C/D ratio section

- Text below the heading seems confusing for HCP and it is not a tool either so we need to display that **We use matrix of data as a source of the C/D ratio results. So when users enter the value of TDD and the value of Trough Level the tool checks in the matrix and returns the result.**
- Info cloud is not active.
- Unit of trough level should be changed to **ng/ml, zakres od 0,1 do 30**
- We should use **commas** in the field instead of dots.
- Unit of Tacrolimus daily dose to be changed from mg to **(mg; od 0,5 do 30)**
- We should use **commas** in the field instead of dots.
- Spell error in heading, it is **Creatinine**
- Its unit should be changed to **(mg/dl)**

**Distribution of the tacrolimus C/D Ratio**

The tool aims at calculating the C/D ratio values and providing a graphical representation. The C/D ratio values are not intended to define the therapeutic strategy but, represent a potentially helpful addition to the clinical monitoring of tacrolimus therapy. The tool calculates the C/D ratio values regardless of the oral tacrolimus formulations (i.e. prolonged-release tablets, immediate- and prolonged- release capsules). Please refer to the list below for a selection of the current literature.

Trough Level (ng/ml)  
6.2

Tacrolimus total daily dose taken (mg)  
3.75

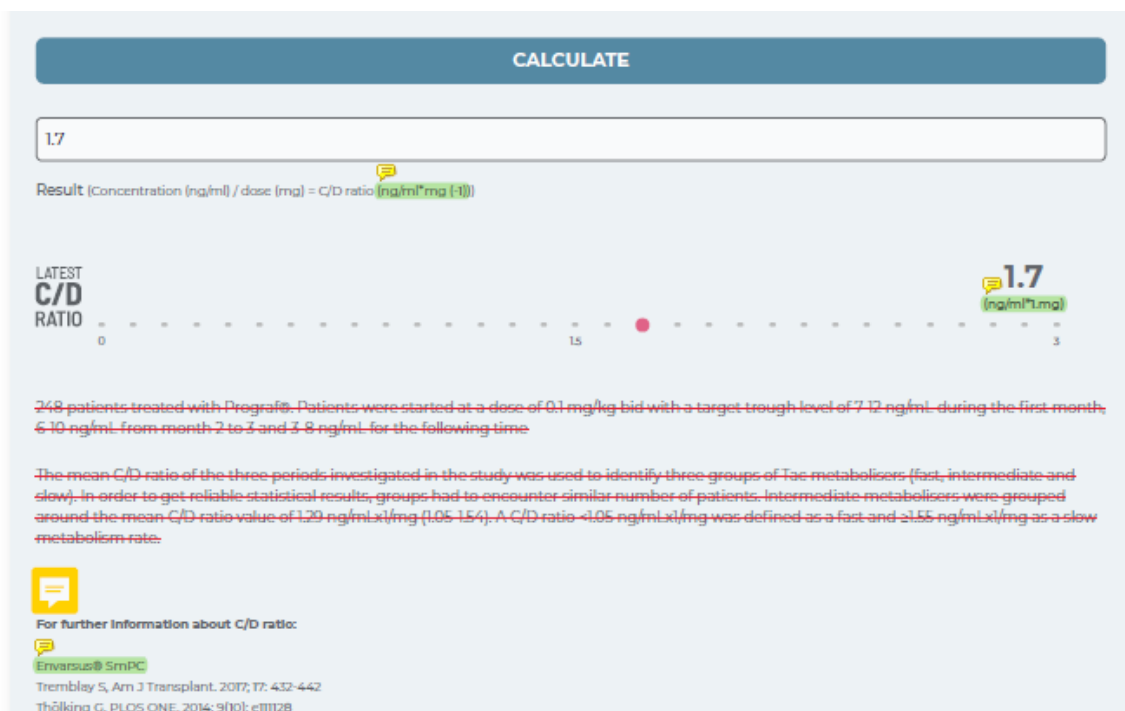
Creatinine (mg/dl)

Date  
17/08/2021

i.

- Below calculate button, in the line Result (Concentration (ng/ml) / dose (mg) = C/D ratio (ng/ml\*mg (-1))) we are using wrong notation , it should be **(ng/ml\*1/mg)**

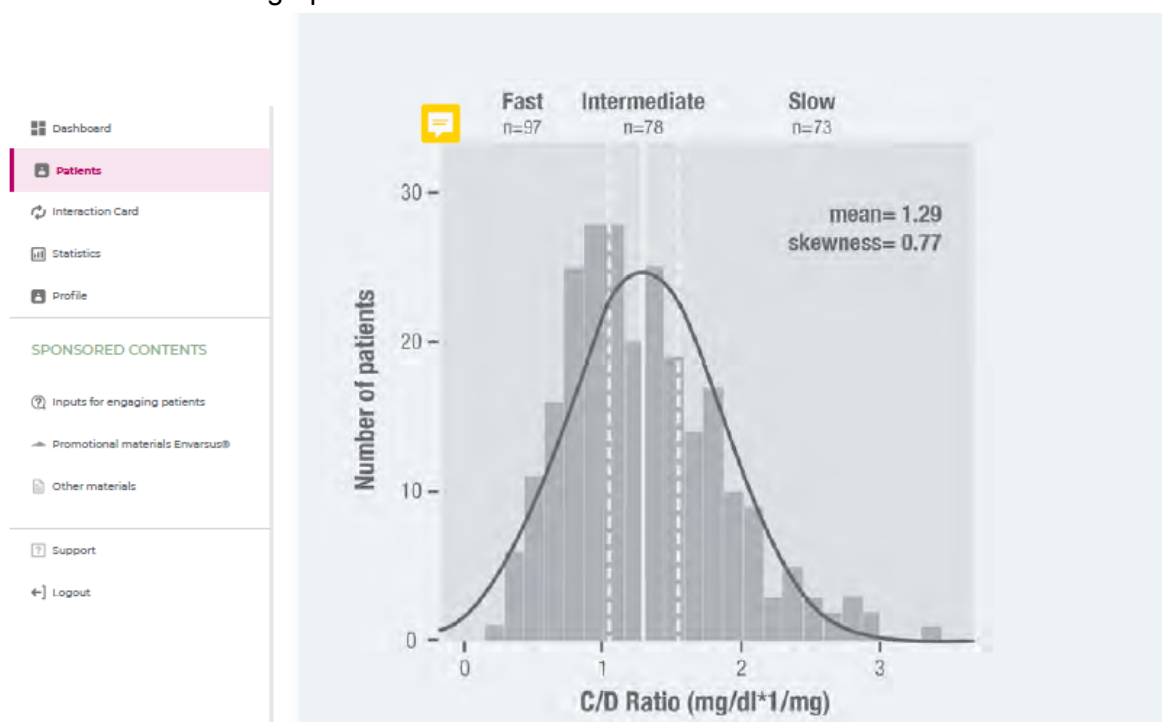
- k. C/D ratio unit to be changed to **(ng/ml\*1/mg)**
- l. Text struck should be deleted.
- m. For further information should be changed to **parametr dodatkowy**
- n. Envarsus® SmPC should be changed to **Charakterystyka Produktu Leczniczego Envarsus®**
- o. sd



p.

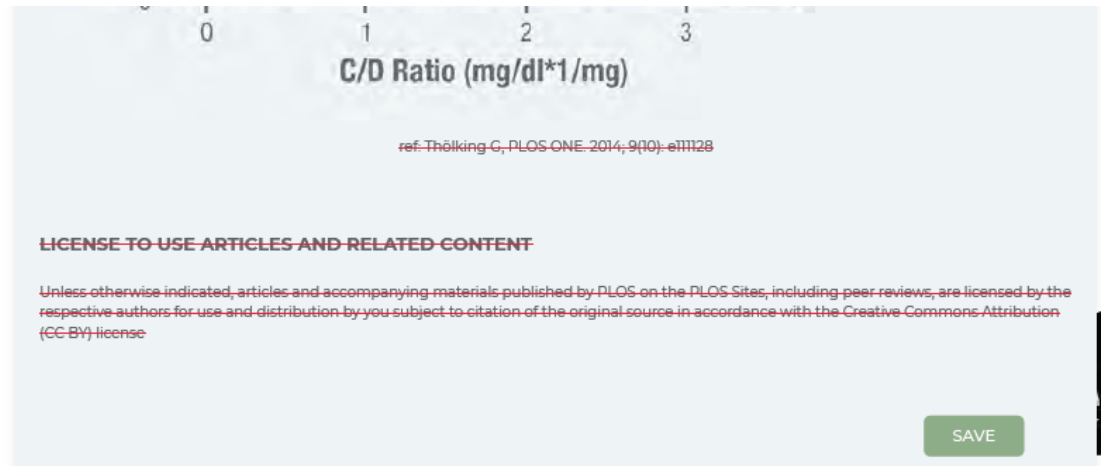
25. To be deleted.

- a. We need to delete this graph.



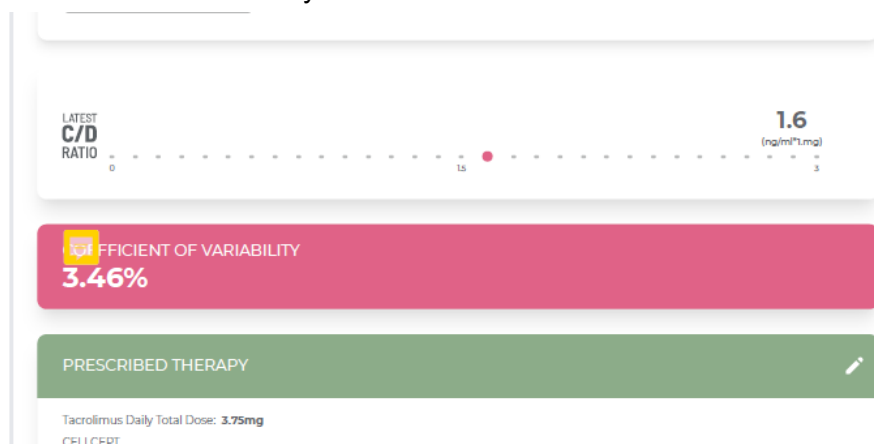
b.

- c. Delete these strike through texts



d.

26. Hide the Coefficient of variability section



a.

27. Need to make changes in Graph.

- Please add the title of the first graph (PL): **Dawka dobowa i stężenia minimalne takrolimusu**
- Change the name of the axis:
  - Total daily dose to **Dawka dobowa takrolimusu (mg)**
  - Trough level to **Stężenie minimalne takrolimusu (ng/ml)**
- Change C/D ratio unit to **(ng/ml\*1/mg)**

d.



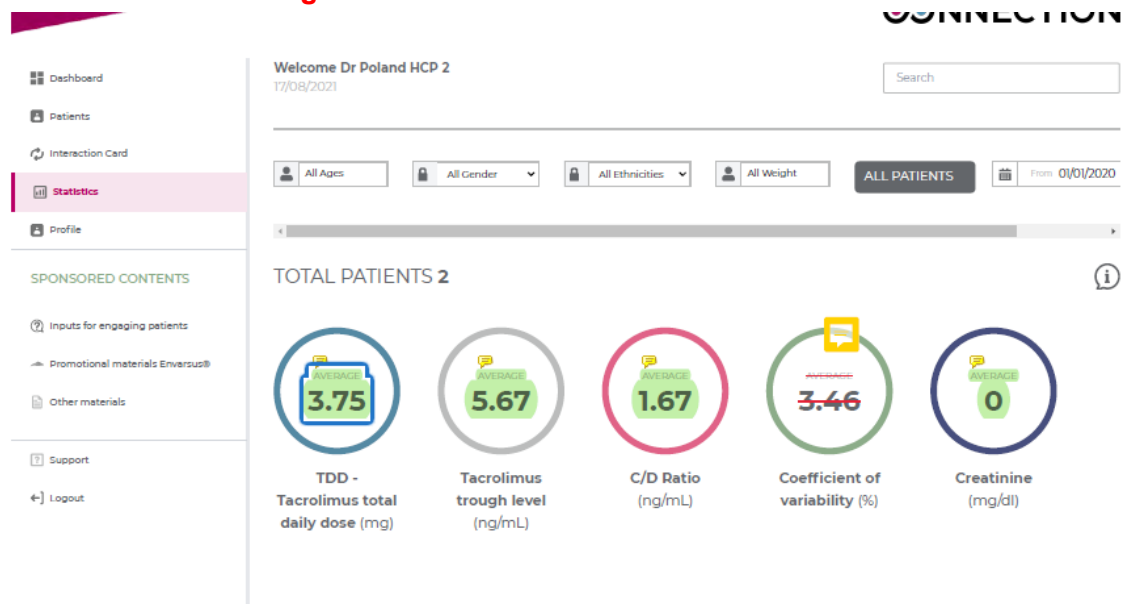
## Changes on Interaction Card

1. We can't use this global version of Interaction card, Custom Card is attached and available at **X Interactions card\_PL (1).xlsx**
2. All strikethrough text should be deleted.

a.

## Changes on Statistics

1. We need to **hide Coefficient of variability (%)**
2. **Average in all circles should be changed to Median.** As we are instructed as **change for median value - it is more relevant then average**
  - a. We need to **Change formula to Median.**



- 3.
4. We need to remove Ethnicity from here.

a.

MEDIAN: 59.50 YRS

**WEIGHT**

RANGE: 64-81

MEDIAN: 72.50 KG

**ETHNICITY**

## Changes on Sponsored Content

- In the Promotional Material section, **the possibility of downloading the promotional content must be disabled!**

Statistics

Profile

SPONSORED CONTENTS

Inputs for engaging patients

Promotional materials Envarsus®

Other materials

Support

Logout

+

All

▼

PODSUMOWANIA BADAŃ

C/D Ratio a utrata przeszczepu

6.

- We need to change text here.

- It should be changed to **OCENA NASILENIA DRŻENIA RĄK**

b.

Pacjenci w wieku podeszłym

FAHN-TOLOSA MARIN SCALE

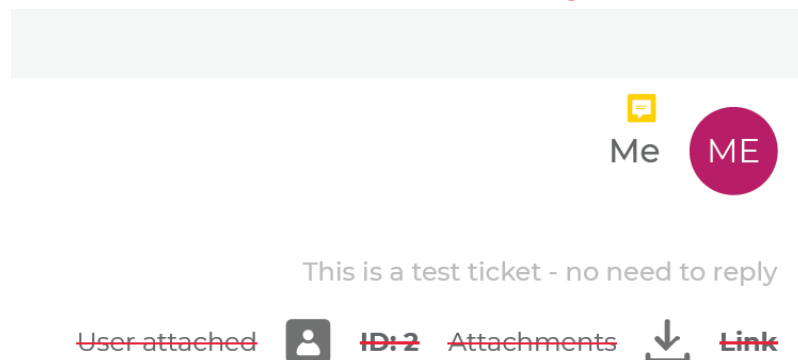
Wstępna ocena nasilenia drżenia rąk

## Changes on Ticket Section

1. This page needs to be simplified. None of the users will make an effort to fill in all these fields - they have no time to do this.
  - a. **leave only 1 and 2**
2. **Remove section 3 & 4**


The screenshot shows a web form titled "OPEN A NEW TICKET". It has four numbered sections: 1. "SUBJECT\*" with a text input field and the instruction "Enter the subject of your request here."; 2. "MESSAGE\*" with a larger text input field and the instruction "Enter your message here."; 3. "SELECT ATTACHMENT" with a file upload icon and the text "ACCEPTED FILE FORMATS: PDF - JPEG - PNG"; 4. "SELECT PATIENT" with a dropdown menu and a small disclaimer text below it: "If user name is related to a patient, please select the patient as reference. Please know that the patient information remains anonymous to the technical team."

- a.
3. In the Chat section, make the following changes.
  - a. **The Pink Icon on the chat should be replaced with something else. Can we put some basic profile avatar there?**
  - b. **ME should be replaced by the name of the account so it can be Dr. Poland HCP 2**
  - c. **Remove all the options which are striked through.**



- i.
- d. Remove all strikethrough things.





Dashboard

Patients

Interaction Card

Statistics

Profile

SPONSORED CONTENTS


Inputs for engaging patients

Promotional materials Enversus®

Other materials

Support

Logout



Welcome Dr Poland HCP 2

17/08/2021

Search


Support Ticket ID: # 2

Time Consumed: 0h 0m

1 minutes ago


Open

1 minutes ago




This is a test ticket - no need to reply

User attached




10-2

Attachments



Link




Tag User

Select...

▼

Select Attachment



ACCEPTED FILE FORMATS: PDF PNG JPG

SUBMIT

e.