



Standard Operating Procedures (SOPs) for Uploading Data into the Adult NorthStar Database

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1.2	22/11/2019	Update following feedback from the PILOT phase of testing system; modified to SOPs for live system	Aleks Pietrusz
1.3	26/10/2021	Revision following the use of active database between March 2021 – October 2021	Aleks Pietrusz
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Table of Contents

LIST OF FIGURES.....	3
1. INTRODUCTION.....	4
2. SETTING UP YOUR LOG IN & ACCESSING THE SYSTEM.....	6
3. MANAGING YOUR ACCOUNT.....	7
4. CREATING A NEW PATIENT RECORD.....	8
4.1. Consent: DMD Patient Consent Form (Adult).....	10
4.2. NEW PATIENT ASSESSMENTS.....	11
4.3. DIFFERENT VIEWS OF A PATIENT RECORD.....	11
<i>Summary tab</i>	11
<i>Timeline tab</i>	12
<i>Documents tab</i>	13
4.4. OTHER MENU OPTIONS.....	14
<i>Manage Primary and Current Centres</i>	14
<i>Manging Assessment Forms</i>	14
5. WHO TO CONTACT.....	15
Appendix 1. DATABASE INTERFACE.....	16
Appendix 2. DATABASE MENU OPTIONS.....	17
Appendix 3. REGISTERING A NEW PATIENT or LINKING AN ADULT PATIENT TO THEIR PAEDIATRIC NORTH STAR DATABASE DATA.....	18
Appendix 4. DATABASE SUBJECT OPTIONS (<i>Summary tab</i>).....	19
Appendix 5. OPTIONS (<i>Timeline, Documents tabs</i>).....	20
Appendix 6. PATIENT SPECIFIC ACTIONS.....	21
Appendix 7. DATABASE ADULT ASSESSMENT FORMS.....	22
Appendix 8. ENTERING / UPLOADING AND SAVING DATA.....	23
Appendix 9. PRINTING COMPLETED ASSESSMENT FORMS.....	24
Appendix 10. TROUBLESHOOTING:.....	25

LIST OF FIGURES

Figure 1. NaND Clarinet home page (if part of multiple networks).	7
Figure 2. NaND Clarinet home page (if part of one network).	7
Figure 3. User options menu.....	7
Figure 4. Menu bar with the Create Patient function.	8
Figure 5 Create Patient function window.	9
Figure 6. Patient details, Timeline tab.	9
Figure 7. Menu specific to each patient.....	10
Figure 8. Patient specific actions.....	10
Figure 9. Patient Summary tab.	12
Figure 10. Patient Timeline tab.....	12
Figure 11. Patient Timeline tab.....	12
Figure 12. Accessing an assessment.	13

1. INTRODUCTION

This document describes how to operate the NaND Clarinet system of the Adult NorthStar Database.

The system offers functionality for:

- Managing patient records and consent forms.
- Uploading patient assessments.
- Accessing assessments as PDF documents.
- Generating administrative reports in PDF format; and generating Excel analysis reports (analysis in Excel on request).
- Currently there is no option available for printing **blank** assessment forms directly from the system (subject to future availability). However, the printable versions of the forms can be downloaded from the OPEN-TACT website (under Network Resources tab) or requested from the Adult NorthStar Network Coordinator.

You can also download this manual from the OPEN-TACT website.

APPLY for an account by visiting the website www.opentact.net and request access. After completing a short form with your details, you will be sent a confirmation email. Follow the instructions in the email.

* Note that OPEN-TACT registration is currently only open to users with an email address from @nhs.net, @nhs.uk or @hscni.net

Adult North Star member training guide.

Step 1. Manual

This manual describes in detail how to operate the NaND Clarinet system of the Adult NorthStar Database. It is a useful resource to refer to while you are using the database.

Step 2. Training video

You can find the training video on how to operate the database and upload patients records on the OPEN-TACT website or request it from the Adult Network Coordinator.

Step 3: A call with the NorthStar Network Coordinator

If you encounter further difficulties with operating the database interface, please contact Adult Network Coordinator to schedule a video or a phone call.

2. SETTING UP YOUR LOG IN & ACCESSING THE SYSTEM

Once the Caldicott Guardian approval is guaranteed at your Trust, please request access to the Adult NorthStar Database with the Adult NorthStar Coordinator. Send the details below with your request:

1. First name and Surname
2. (optional) title (Ms, Mrs, Mr, Dr)
3. NHS email address (*You can only access the database using your NHS email address and from an NHS computer*)
4. Organisation
5. Job role

Following that you will receive an email with a link to set up a password.

The link is valid for **48 hours**. If you missed the email, click on '**click here to request a new password**' (link in the same email).

NaND Clarinet is available at the following URL:

<https://secure.certus-tech.com/nnd/>

When you first access the system, use the '**Forgotten your password?**' feature. You will be emailed a temporary password, which you should **change immediately**. (If you do not already have an account then you must contact your local NaND administrator/ the Adult Network Coordinator and request an account). Please notify the coordinator if you **already have a paediatric account** linked to your NHS email address.

Your account will be set up with specific privileges to access functions appropriate to your role. You will also be associated with your organisation and specific disease groups (if you are part of any other network). This determines which patient records will be visible to you.

3. MANAGING YOUR ACCOUNT

On logging in, a user will see the patient listing page for a disease group (Figure 1). This view is referred to as **the Project Explorer** view (as each patient is represented in the system by a distinct, independently managed project).

The disease group tabs can be seen at the top right of the page, with the current tab coloured green (Figure 1).

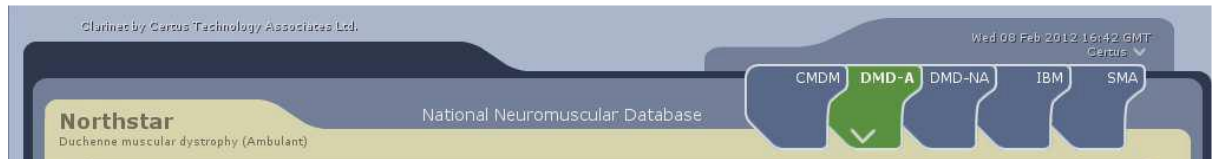


Figure 1. NaND Clarinet home page (if part of multiple networks).

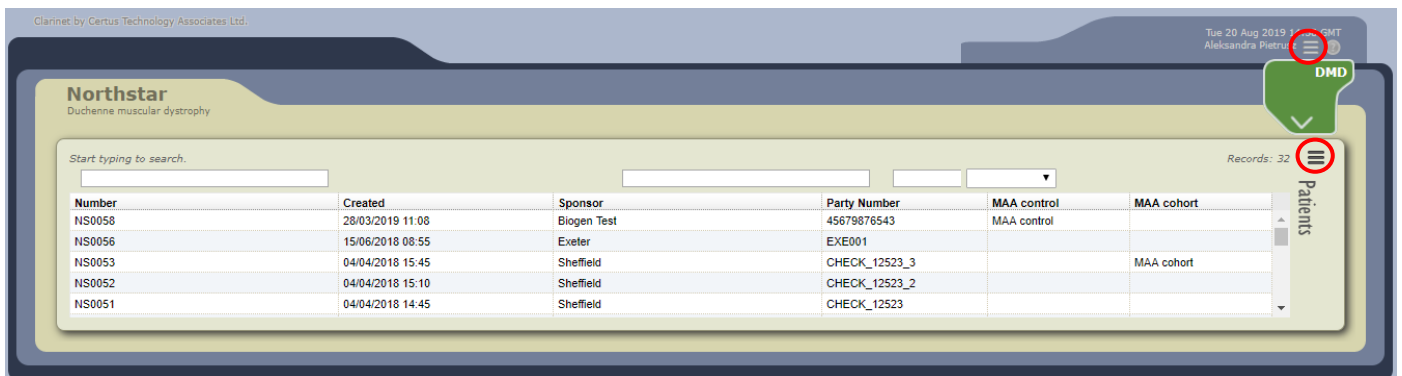


Figure 2. NaND Clarinet home page (if part of one network).

Two menus are available from this page – two horizontal lines tabs, circled in red in Figure 2. The menu items available will depend on your privileges.

The home page can be reached at any time by selecting **the Project Explorer** menu option.

Any queries related to entered data will appear under **the Tasks** option.

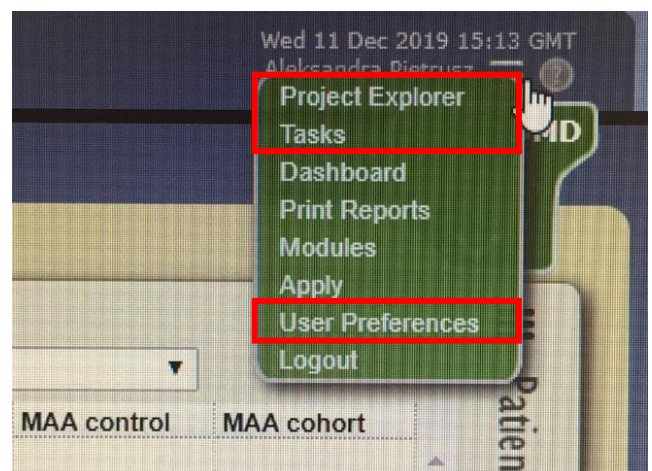


Figure 3. User options menu.

You can change your password at any time under **the User Preferences**. For security reasons, the system will not allow you to reuse an earlier password set on your account.

The account is specific to you and must never be used by anyone else. It is the basis of audit logs and is used to track who made which changes.

If you leave your organisation, then the account will be changed or suspended as appropriate.

4. CREATING A NEW PATIENT RECORD

To create a new patient record, select the **Create Patient** menu option from the second menu bar circled in red in Figure 4. You will be asked for the NHS number of the patient you want to add (Figure 5).

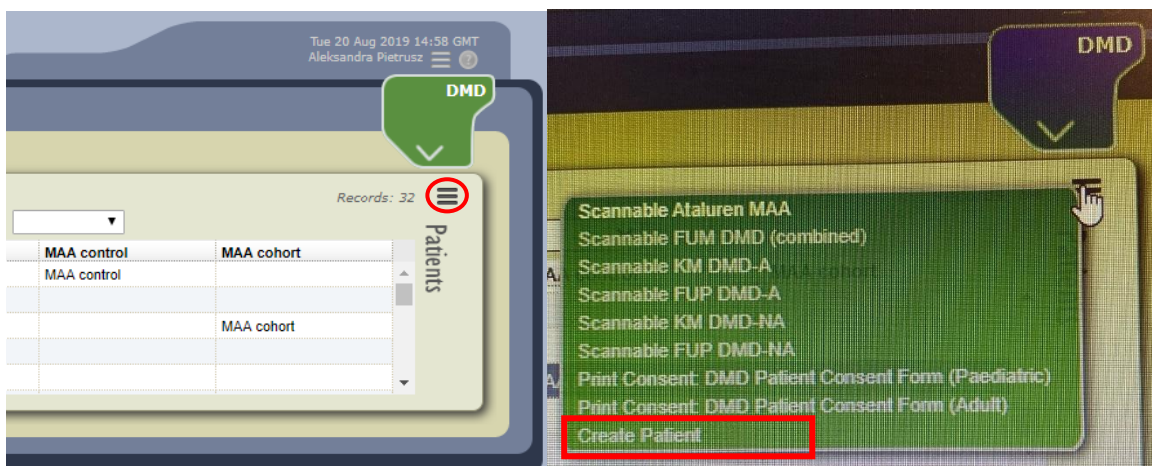


Figure 4. Menu bar with the **Create Patient** function.

- If the patient is **new to the database**, the system will automatically allocate a unique NaND number for him. This will be used on all assessment forms to identify the patient without disclosing Patient Identifiable Information (PII).
- If the patient **previously participated** in the Paediatric NorthStar database, the system will automatically link their adult profile to their paediatric profile through their NHS number.
 - **However**, you will need to request from the Adult NorthStar Network

Coordinator to transfer those patients first from their paediatric services to adult services.

- This is because each centre can only see their own patients.
- Please send **NHS numbers only** to the Adult NorthStar Network Coordinator.

Figure 5 Create Patient function window.

Once created, the new patient will appear at the top of the patient list. To assist with searching, you can type information in the search boxes. When you see the patient in the listing, **click on it to select**. A patient detail section will open below (see Figure 6).

Number	Created	Sponsor	Party Number	Consent	Type
NS0145	15/03/2022 16:11	(Adult) UCLH	458067532	✓	Adult patient
NS0144	11/01/2022 10:09	(Adult) UCLH	605938593	✓	Adult patient
NS0143	10/06/2021 13:34	(Adult) UCLH	288348263	✓	Adult patient
NS0142	02/06/2021 15:21	(Adult) UCLH	0493479328	✓	Adult patient
NS0141	27/04/2021 15:39	(Adult) UCLH	69430803298	✓	Adult patient

Figure 6. Patient details, *Timeline* tab.

Once patient is selected the **third menu option** (for the specific patient) will become available (red circle in Figure 7).

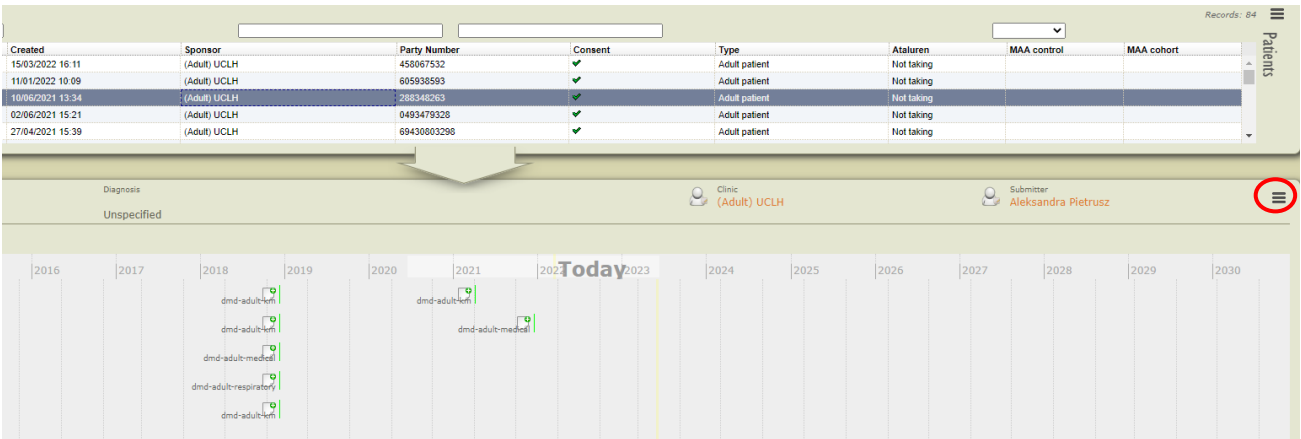


Figure 7. Menu specific to each patient.

Patient specific assessment forms and the Adult NorthStar consent form will become available (Figure 8)

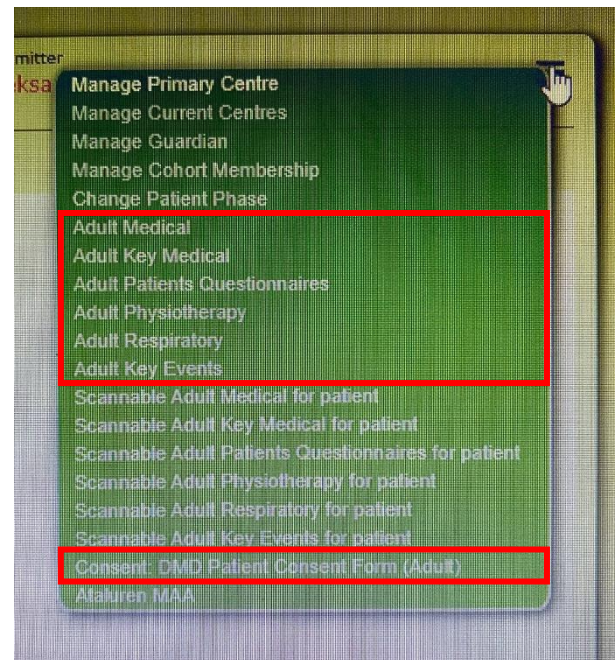


Figure 8. Patient specific actions.

4.1. Consent: DMD Patient Consent Form (Adult)

You **must** obtain consent from **all adult patients in writing**. Following that you can record it electronically in NaND. This includes patients who were included in the paediatric database. Both paediatric and adult consents should be recorded and will be stored on the NorthStar Database.

The **Adult Consent form** can be found on the NaND under the second menu bar,

under **Consent: DMD Patient Consent Form (Adult)** tab (Figure 8), on the OPEN-TACT website or requested from the Adult NorthStar Network Coordinator. You will need to paste the consent form on to the hospital letterhead template.

Please keep the signed and dated original copy in patients' medical records and safely at the Trust and give a copy to the patient.

4.2. NEW PATIENT ASSESSMENTS

- A. You can fill in the assessment forms directly online during patient's appointment.
- B. Or you can print out the paper version of the assessments and enter data electronically later.

There is one button for each assessment type. The form will appear in a separate window, with a **Submit** button at the end of the form.

Once submitted, the form will appear on the **Timeline**. It can be viewed and edited. The information in the form will be stored in the database and, provided consent has been set, used in any subsequent reporting.

4.3. DIFFERENT VIEWS OF A PATIENT RECORD

Three tabs (*Summary*, *Timeline* and *Documents*) offer you access to different views over a patient record.

Summary tab

The patient **Summary** tab gives an overview of selected, recent information about the patient. It will comprise a dashboard report designed by the clinical team. An example is depicted in the Figure 9 below. Hovering over each icon will give you further details. For example, hovering over a point on the graph will give you the value at that point.

This section of the database will be revised for the adult population in the future.



Figure 9. Patient Summary tab.

Timeline tab

The **Timeline** tab shows the key events and all completed assessments (Figure 10).

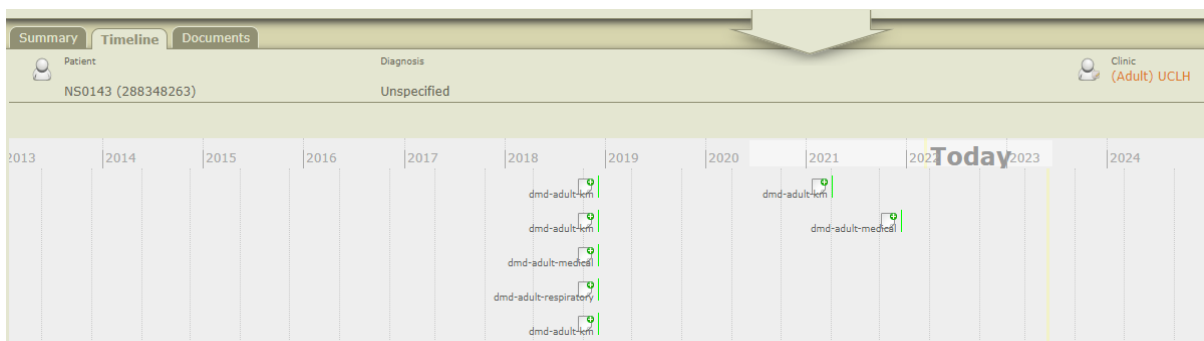


Figure 10. Patient Timeline tab.

This view is designed for patient management, including assessment planning. It is possible to show any event on the **Timeline**, including steroid start and stop dates and hospital events (Figure 11). The shading, for example, indicates that steroids are being taken during this period.



Figure 11. Patient Timeline tab.

It is also possible to access details of each assessment from this view and update an online assessment. Simply click on the '+' sign to the top right of the required assessment (see Figure 12).

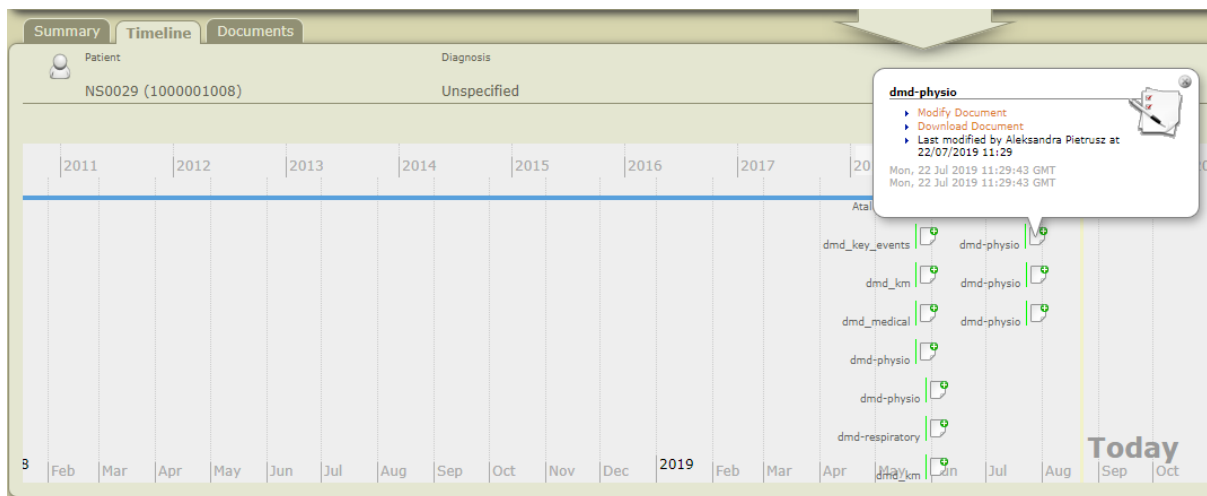


Figure 12. Accessing an assessment.

The dates at the bottom indicate the date the assessment was completed and/or modified on the system. Using the options above, you can further *Modify* or *Download* the document.

Documents tab

This is an old database function, created for the paediatric database to upload the scannable assessment forms. The adult database does not currently support uploading scannable forms. However, if the adult patient is linked to their paediatric records, you will be able to see the past scannable assessment forms as pdf documents.

4.4. OTHER MENU OPTIONS

Depending on your privileges, three other menu options may be available to you. We describe each in turn.

Manage Primary and Current Centres

Patients can **move between centres** as well as, they can attend **more than one at the time** (e.g. muscle clinic, respiratory clinic, cardiology clinic all based in different hospitals) and NaND must be updated accordingly. NaND administrators have the privilege required to move a patient from one Trust to another or to add another Trust under patient's records. Please contact them if the above is required at your Trust.

Manging Assessment Forms

- Considering the same patient, two different assessment forms (e.g. MEDICAL and PHYSIOTHERAPY forms) can be open **at the same time** by **different users** on **different devices**.

HOWEVER

- Considering the same patient, the same assessment form (e.g. MEDICAL) **must NOT be open on 2 different devices at the same time**.
 - If two users each create a new MEDICAL assessment for the same patient but for different dates, then there will be no problem.
 - If the two users try to create a new MEDICAL assessment for the same patient for the same date, then the first submitted will work; the other will be denied as a duplicate.
 - If two users each edit the same assessment at the same time from the Timeline then there will be a problem. The submissions will clash; one will be saved and the other lost.

5. WHO TO CONTACT

If you continue having problems with resetting your password, or any problems operating the Database in general, please contact Adult NorthStar Network Coordinator:

Aleksandra Pietrusz,
Adult NorthStar Database Coordinator
a.pietrusz@ucl.ac.uk

Appendix 1. DATABASE INTERFACE

Clannet by Certus Technology Associates Ltd. Tue 20 Aug 2019 14:58 GMT Aleksandra Pietrusz

Northstar
Duchenne muscular dystrophy

National Neuromuscular Database

Start typing to search. Records: 32

Number	Created	Sponsor	Party Number	Consent	Type	Ataluren	MAA control	MAA cohort
NS0058	28/03/2019 11:08	Biogen Test	45679876543	✓	Non-ambulant patient	Taking	MAA control	
NS0056	15/06/2018 08:55	Exeter	EXE001	✗	Ambulant patient	Taking		
NS0053	04/04/2018 15:45	Sheffield	CHECK_12523_3	✗	Non-ambulant patient	Not taking		MAA cohort
NS0052	04/04/2018 15:10	Sheffield	CHECK_12523_2	✗	Non-ambulant patient	Not taking		
NS0051	04/04/2018 14:45	Sheffield	CHECK_12523	✗	Ambulant patient	Not taking		

Number: Patient's NorthStar Number

Created: Date when patient created on the Database

Sponsor: Patient's Primary Trust

Type: Adult patient

Ataluren: Participation status

DMD: Projects you work on (e.g. if you are part of the SMA smart net, you will be able to see it here as a separate tab)

Appendix 2. DATABASE MENU OPTIONS

The image shows a screenshot of a web application interface. A menu is open, listing several options: Project Explorer, Tasks, Dashboard, Print Reports, Modules, Apply, User Preferences, and Logout. Red boxes highlight 'Project Explorer', 'Tasks', and 'User Preferences'. A red line connects these boxes to a larger menu icon in the top right corner of the application. Another red box highlights the 'Create patient' option in a separate screenshot, with a red line connecting it to a callout box.

Project Explorer: Takes you to the list of projects you work on.

Tasks: Takes you to the list of the queries based on your data entry.

User Preferences: Where you can change account settings and change password.

Create patient: Where you add a new patient or link patient with the paediatric NorthStar Database number based on their NHS number.

Appendix 3. REGISTERING A NEW PATIENT or LINKING AN ADULT PATIENT TO THEIR PAEDIATRIC NORTH STAR DATABASE DATA.

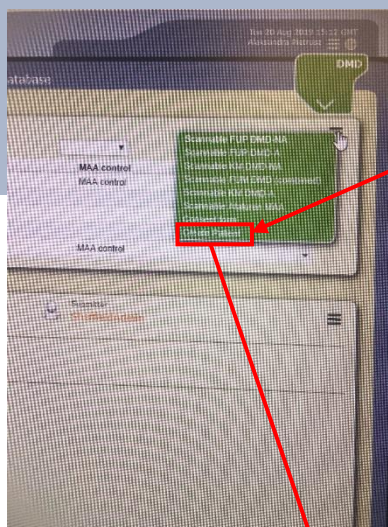
Northstar
Duchenne muscular dystrophy

National Neuromuscular Database

Start typing to search.

Records: 23

Number	Created	Sponsor	Party Number	Consent	Type	Ataluren	MAA control	MAA cohort
NS0058	28/03/2019 11:00	Biogen Test	45679876543	✓	Non-ambulant patient	Taking	MAA control	MAA cohort
NS0056	15/06/2018 08:55	Exeter	EXE001	✗	Ambulant patient	Taking		
NS0053	04/04/2018 15:45	Sheffield	CHECK_12523_3	✗	Non-ambulant patient	Not taking		MAA cohort
NS0052	04/04/2018 15:10	Sheffield	CHECK_12523_2	✗	Non-ambulant patient	Not taking		
NS0051	04/04/2018 14:45	Sheffield	CHECK_12523	✗	Ambulant patient	Not taking		



Create patient: to add a new patient or link with the paediatric NorthStar Database number

National Neuromuscular Database

Create Patient

New Patient

Patient details are visible to employees of your clinic and system administrators.

NHS Number Enter the patient NHS number.

Clinic Defaults to your own clinic if left blank

Submit

Diagn
Uns

Enter patient's NHS number. Patients who were part of the paediatric NorthStar Database will be linked through their NHS number

Appendix 4. DATABASE SUBJECT OPTIONS (*Summary* tab)

Clannet by Certus Technology Associates Ltd. Tue 20 Aug 2019 15:13 GMT
Aleksandra Pietrusz

Northstar National Neuromuscular Database
Duchenne muscular dystrophy DMD

Start typing to search. Records: 32

Number	Created	Sponsor	Party Number	Consent	Type	Ataluren	MAA control	MAA cohort
NS0056	15/06/2018 08:55	Exeter	EXE001	✗	Ambulant patient	Taking		
NS0029	18/02/2016 00:00	Sheffield	1000001008	✓	Adult patient	Taking		
NS0005	15/09/2015 01:00	Sheffield	245235636	✗	Non-ambulant patient	Not taking		
NS0030	23/02/2016 00:00	Sheffield	6528086702	✗	Ambulant patient	Taking		
NS0031	21/10/2016 01:00	Sheffield	1000010007	✗	Ambulant patient	Taking		

Summary | Timeline | Documents

Patient: NS0029 (1000001008) | Diagnosis: Unspecified | Clinic: Sheffield | Submitter: SheffieldAdmin

Steroid: Summary | Current Dose: Unspecified | Side Effects: Unspecified

Assessments: Key Medical, Medical (3), Physio (0)

Weight: [Graph area]

Type: This MUST state: Adult patient

- Summary of:**
- Diagnosis
 - Primary Clinic
 - Steroid use
 - Side effects
 - Type, date and number of completed assessments

Appendix 5. OPTIONS (*Timeline, Documents* tabs)

Northstar
Duchenne muscular dystrophy

National Neuromuscular Database

Start typing to search.

Records: 32

Number	Created	Sponsor	Party Number	Consent	Type	Ataluren	MAA control	MAA cohort
NS0058	28/03/2019 11:08	Biogen Test	45679876543	✓	Non-ambulant patient	Taking	MAA control	
NS0056	15/06/2018 08:55	Exeter	EXE001	✗	Ambulant patient	Taking		
NS0053	04/04/2018 15:45	Sheffield	CHECK_12523_3	✗	Non-ambulant patient	Not taking		MAA cohort
NS0052	04/04/2018 15:10	Sheffield	CHECK_12523_2	✗	Non-ambulant patient	Not taking		
NS0051	04/04/2018 14:45	Sheffield	CHECK_12523	✗	Ambulant patient	Not taking		

Summary | **Timeline** | Documents

Patient: NS0029 (1000001008) | Diagnosis: Unspecified | Clinic: Sheffield | Submitter: SheffieldAdmin

Timeline: 2011-2028. Events include Ataluren MAA, dmd_key_events, dmd_km, dmd_medical, dmd-physio, and dmd-respiratory.

Timeline: shows all the completed assessment on the timeline.

- When Key Events Form is completed, the info gets populated to the Timeline
- You can click on the individual assessments to **modify** them (records of who and when it was audited is recorded) OR to **download** them
- **Green HORIZONTAL line:** appears if there was a delay with entering data; **green VERTICAL line:** if the assessment data was entered immediately
- **Blue line:** indicates the length of Ataluren participation

Documents: old tab where scannable forms used to be uploaded. It won't be used in the Adult NorthStar Database.

Appendix 6. PATIENT SPECIFIC ACTIONS.

Northstar
Duchenne muscular dystrophy

National Neuromuscular Database

Start typing to search.

Number	Created	Sponsor	Party Number	Consent	Type	Ataluren	MAA control	MAA cohort
NS0056	15/06/2018 08:55	Exeter	EXE001	✗	Ambulant patient	Taking		
NS0029	18/02/2016 00:00	Sheffield	1000001008	✓	Adult patient	Taking		
NS0005	15/09/2015 01:00	Sheffield	245235636	✗	Non-ambulant patient	Not taking		
NS0030	23/02/2016 00:00	Sheffield	6528086702	✗	Ambulant patient	Taking		
NS0031	21/10/2016 01:00	Sheffield	1000010007	✗	Ambulant patient	Taking		

Records: 32

Summary | Timeline | Documents

Patient: NS0029 (1000001008) | Diagnosis: Unspecified | Clinic: Sheffield | Submitter: SheffieldAdmin

Steroid Summary

Current Dose: Unspecified

Assessments: Key Medical, Medical (3), Physio (0)

Consent: DMD Patient Consent Form (Adult): registering consent.

Manage Primary Centre – lead Trust:

- Can give/remove permission (add/remove another Trust) to share patients' records by adding other Clinics.
- Based on patient's consent.
- Must be requested with the NorthStar Coordinator.

Manage Current Centres – list of clinics involved in subjects' care.

Manage Cohort Membership:

- Ataluren, MAA control, MAA cohort (only people involved in these projects will be able to access that information).

Change Patient Phase: this will be changed by the NorthStar Coordinator when transferring paediatric patients to adult centres.

SOPs For Uploading Data into the Adult NorthStar Database version 1.4 01/June/2022

Appendix 7. DATABASE ADULT ASSESSMENT FORMS

Clarinet by Certus Technology Associates Ltd. Tue 20 Aug 2019 15:13 GMT
Aleksandra Pietruz

Northstar
Duchenne muscular dystrophy National Neuromuscular Database

Start typing to search. Records: 32

Number	Created	Sponsor	Party Number	Consent	Type	Ataluren	MAA control	MAA cohort
NS0056	15/06/2018 08:55	Exeter	EXE001	✗	Ambulant patient	Taking		
NS0029	18/02/2016 00:00	Sheffield	1000001008	✓	Adult patient	Taking		
NS0005	15/09/2015 01:00	Sheffield	245235636	✗	Non-ambulant patient	Not taking		
NS0030	23/02/2016 00:00	Sheffield	6528086702	✗	Ambulant patient	Taking		
NS0031	21/10/2016 01:00	Sheffield	1000010007	✗	Ambulant patient	Taking		

Summary | Timeline | Documents

Patient: NS0029 (1000001008) | Diagnosis: Unspecified | Clinic: Sheffield | Submitter: SheffieldAdmin

Current Dose: Unspecified | Side Effects: Unspecified

Assessments: Key Medical | Medical (3)

- Manage Primary Centre
- Manage Current Centres
- Manage Guardian
- Manage Cohort Membership
- Change Patient Phase
- Adult Medical
- Adult Key Medical
- Adult Patients Questionnaires
- Adult Physiotherapy
- Adult Respiratory
- Adult Key Events
- Scannable Adult Medical for patient
- Scannable Adult Key Medical for patient
- Scannable Adult Patients Questionnaires for patient
- Scannable Adult Physiotherapy for patient
- Scannable Adult Respiratory for patient
- Scannable Adult Key Events for patient
- Consent: DMD Patient Consent Form (Adult)

Adult Medical: different to paed; appropriate data fields harmonised with paediatric form.

Adult Key Medical: only for New Patients, who were not registered in the paediatric NorthStar Database.

Adult Patient Questionnaires: need to be printed out and given to patients in the waiting room.

Adult Physiotherapy: the same form between paed and adults; one form for all patients.

Adult Respiratory: the same between paed and adults.

Adult Key Events: a separate page; also included in Adult Medical form.

Appendix 8. ENTERING / UPLOADING AND SAVING DATA

Select a correct form from the list.

The screenshot shows the 'National Neuromuscular Database' interface. At the top, there is a search bar and a table of patients. The table has columns for Number, Created, Sponsor, Party Number, Consent, Type, Ataluren, MAA control, and MAA cohort. The patient NS0029 is highlighted. Below the table, there is a patient summary section for NS0029 (1000001008) with fields for Steroid Summary, Current Dose, Assessments, Medical, and Physio. A dropdown menu is open, showing a list of forms. The 'Adult Medical' section is highlighted with a red box, and the 'Adult Physiotherapy' form is selected. A red arrow points from the dropdown menu to the 'SAVE' button in the next screenshot.

Number	Created	Sponsor	Party Number	Consent	Type	Ataluren	MAA control	MAA cohort
NS0058	15/06/2018 08:55	Exeter	EXE001	✗	Ambulant patient	Taking		
NS0029	15/06/2018 09:00	Sheffield	1000001008	✓	Adult patient	Taking		
NS0045	15/06/2018 01:00	Sheffield	245236836	✗	Non-ambulant patient	Not taking		
NS0030	23/02/2016 09:00	Sheffield	6520869702	✗	Ambulant patient	Taking		
NS0031	21/10/2016 01:00	Sheffield	1000010007	✗	Ambulant patient	Taking		

- Manage Primary Centre
- Manage Current Centres
- Manage Guardian
- Manage Cohort Membership
- Change Patient Phase
- Adult Medical
- Adult Key Medical
- Adult Patients Questionnaires
- Adult Physiotherapy
- Adult Respiratory
- Adult Key Events
- Scanable Adult Medical for patient
- Scanable Adult Key Medical for patient
- Scanable Adult Patients Questionnaires for patient
- Scanable Adult Physiotherapy for patient
- Scanable Adult Respiratory for patient
- Scanable Adult Key Events for patient
- Consent - DMD Patient Consent Form (Adult)
- Release MAA

For example, select an Adult Physiotherapy form:

The screenshot shows the 'Project Form' dialog box. The 'Subject Details' section is expanded, showing 'Subject ID' as NS0038 and 'Centre Name' as O9003. Other sections include Appointment, Patient Information, Perception of general health and wellbeing of the patient, North Star Ambulatory Assessment, and Transition Assessment North Star Worksheet. At the bottom of the dialog box, there are two buttons: 'SAVE DRAFT' and 'SAVE'. A red arrow points from the 'SAVE' button in the previous screenshot to this 'SAVE' button.

Project Form | NND Clarinet - Google Chrome
nnd.test.certus-tech.com/nnda/cla/projectform/load_form/BESD0FCD0A00027D018C633E1148B046_ActivityRequest_dmd-physio

Project Form

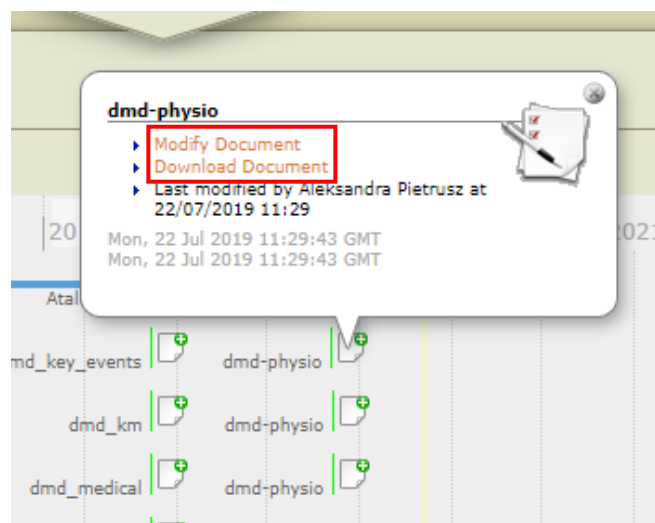
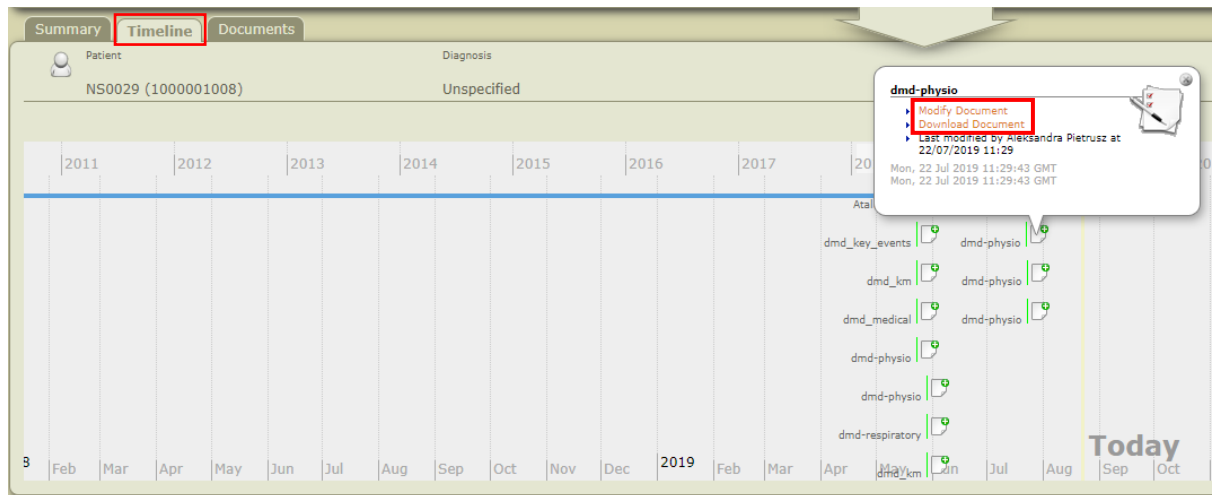
Subject ID: NS0038
Centre Name: O9003

SAVE DRAFT SAVE

Once completed, select 'Save' button.

Appendix 9. PRINTING COMPLETED ASSESSMENT FORMS

Once the assessment is completed and saved, it will appear on the *Timeline*. You can select individual assessments from the *Timeline* and: 'Download' for printing or 'Modify'. The person and time of assessment editing will be recorded.



Appendix 10. TROUBLESHOOTING:

FORGOTTEN PASSWORD

If you forget your password, you can reset it by clicking on the 'Forgotten your password?' option underneath the log in fields as below:



National Neuromuscular Database

Login to your account

Username or email address:

Password:

LOGIN **Forgotten your password?**

This web site is a private site operated and maintained by Certus Technology. Access to this site is restricted, unauthorised login attempts are logged and legal action may be taken against those attempting to illegally access this system.


If you are having problems using this system, please report them via the Issue Management System or via mail to nd.support@certus-tech.com

- Do not disclose your password to anyone
- Do not keep your password written down near to your computer.

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Following that enter your NHS email, which you are registered with on the NorthStar Database.



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Don't know your password?

If you do not know the password to your account, please enter your email address or username. You will be sent an email which allows you to set your password.

Enter email address/username

| Remembered your password?