

A photograph of Northwestern University buildings in Chicago. The image features a prominent Gothic Revival style tower with a crenellated top and a modern glass skyscraper to its right. A large, semi-transparent purple triangle is overlaid on the left side of the image, containing white text.

**M Northwestern Medicine**<sup>®</sup>  
Feinberg School of Medicine

## NU IMPACT Study:

*Recruiting and Consenting  
through the EDW in REDCap*

CCCR-CTRIS, October 19<sup>th</sup>, 2021  
Nikki Lancki, Senior Statistical Analyst  
Michael Bass, Research Associate Professor

# Outline

- NU IMPACT – background and study design
- Automation and System Integration used for Study Workflows



- Recruitment from EDW



- eConsent and survey-based longitudinal assessments in Redcap



- Study Tracker and Epic Integration

# NU IMPACT Study Overview

- Northwestern University's NU IMPACT builds upon an existing and EHR-integrated cancer symptom monitoring and management system (NMPRO)
- Test the effectiveness of a system-wide symptom management intervention when implemented across the Northwestern Memorial HealthCare Corporation (NMHC) outpatient oncology clinics using a clinic-level randomized roll-out implementation trial design, and embedded patient-level randomized controlled clinical trial (RCT)
  - The enhanced care (EC) approach aims to engage participants actively, and to increase self-efficacy in the monitoring and managing of their symptoms
  - The existing NMPRO constitutes usual care (UC)

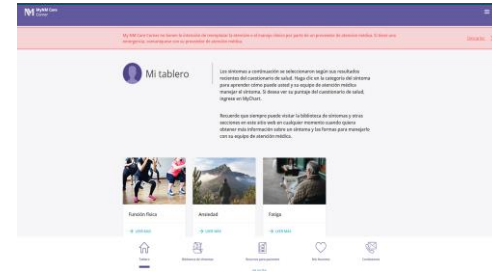
# NU IMPACT Study Design

## Hybrid Type II Effectiveness-Implementation Trial

1. Clinic-level pragmatic randomized roll-out implementation trial (N=12,000; n=6,000 Pre-I & 6,000 Post-I)
  - Modified stepped-wedge (“staircase”)
  - System-level implementation evaluation
  - Draw comparisons within and between sites via evaluation of implementation of NMPRO usual care (UC), NU IMPACT intervention (EC)
2. Patient-level randomized controlled clinical trial (n = 6,000)
  - Embedded in the post-implementation phase
  - Group-based comparison of usual care (UC; n=3,000) vs. enhanced care (EC; n=3,000)
  - Primary outcomes are individual PROs over time

# NU IMPACT – Workflow/Features to Consider

- Large volume of participants to recruit through EDW
- Electronic consent and survey-based patient-level data collection
- Randomization (gender, language, site, cancer continuum)
- Clinical units going live and pre to post implementation over time



# NU IMPACT – Software system overview

## Research Systems

REDCap:  
Research Data  
Collection System

Study Tracker:  
Trial Management  
System

NU IMPACT website  
Enhance Care

Electronic Data  
Warehouse

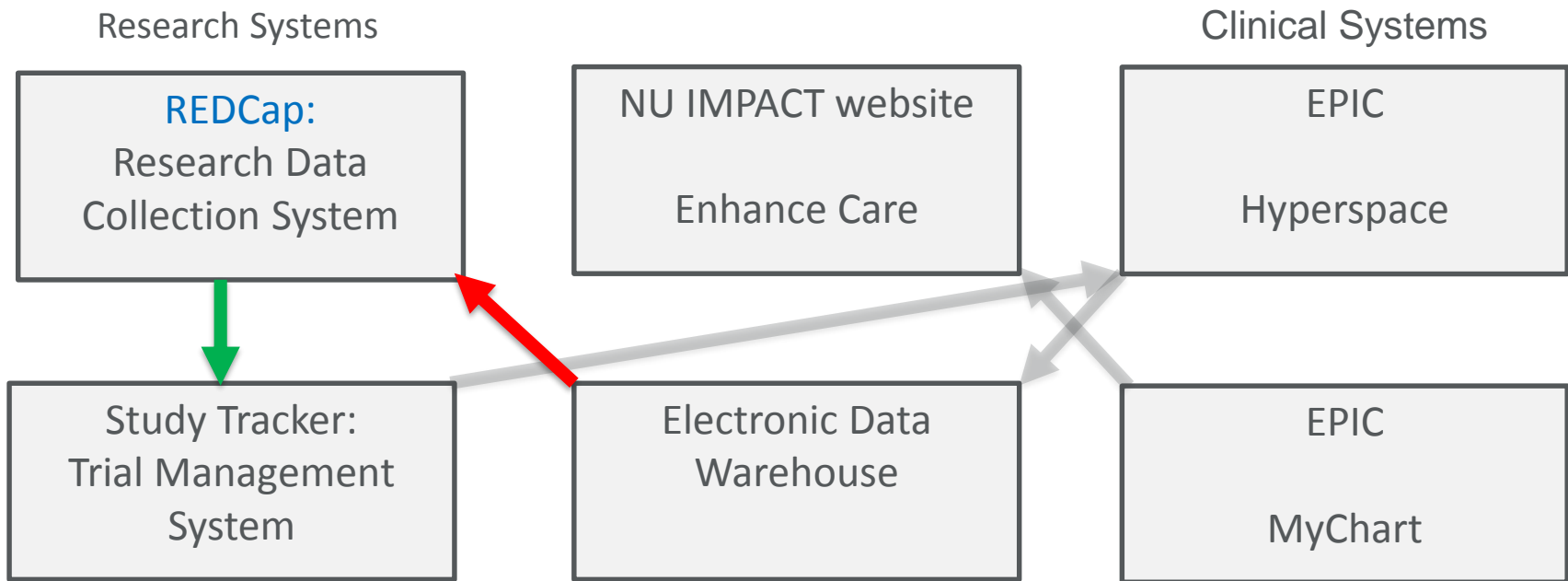
## Clinical Systems

EPIC  
Hyperspace










EPIC  
MyChart

# NU IMPACT – Data Flow

Recruitment  
Consent  
Compliance



# NU IMPACT – REDCap Projects

NU IMPACT		2,178	1,795	5 forms 43 surveys		
NU IMPACT Staging (Recruitment and Randomization)		22,891	3,200	4 forms 45 surveys		
NU IMPACT Spanish		9	1,832	3 forms 43 surveys		




# EDW Recruitment: Identifying eligible patients

- Northwestern Medicine Enterprise Data Warehouse (NMEDW) is the integrated repository of clinical and research data for NMHC and NU FSM
- Worked with EDW analyst (Quan Mai) to identify eligible patients:
  - Cancer diagnosis in medical record (ICD-9/ICD-10 code on problem list or encounter diagnosis) within past 10 years
  - Visit to clinic in past year
  - Age  $\geq 18$  years
  - Additional eligibility:
    - Has valid email address
    - Provider agreed to patients being contacted
    - Seen by those providers at the departments (clinic sites) currently recruiting from

# EDW Recruitment: Automation

- Goal was daily upload of identified eligible participants from EDW
- Added EDW data architect and nmedw\_webservice to REDCap project
- Requested API token on behalf of nmedw\_webservice

Role name <small>(click role name to edit role)</small>	Username or users assigned to a role <small>(click username to edit or assign to role)</small>	Expiration <small>(click expiration to edit)</small>	Project Design and Setup	User Rights	Data Access Groups	Data Export Tool	Reports & Report Builder	Graphical Data View & Stats	Survey Distribution Tools	Calendar	Data Import Tool	Con
---	nmedw_webservice (nmedw_webservice nmedw_webservice) 	never	✗	✗	✗	Full Data Set	✓	✓	✓	✓	✓	

- Data architect created daily ETL (extract, transform, and load) process:
  - Run EDW analyst query that identifies eligible participants in EDW and fields for recruitment
  - Check REDCap database to compare if patient already in the current REDCap project (prevents overwriting)
  - Import eligible participant information and recruitment fields into REDCap

# Automation of Recruitment Email

- REDCap project for upload of EDW recruitment data and consent/baseline data collection
- When new data is uploaded, use REDCap Automated Survey Invitation (ASI) logic to send email with link to Consent
- Use REDCap survey queue and auto-continue to continue into baseline assessment
- Enabled reminders if no response

# Automation of Recruitment Email

**Define Conditions for Automated Survey Invitations (ASI)**

**Instructions:** In this pop-up you may define your conditions for automated survey invitations that will be sent out for the survey (and event, if a longitudinal project) listed in the info box below. [Tell me more](#)

**Info**  
**Survey title:** Consent to Participate in NU IMPACT Study/Consentimiento para participar en el estudio NU IMPACT

**STEP 1: Compose message**

From: [Display name (optional)] nuimpact@northwestern.edu  
(select any project user to be the 'Sender')

To: [All participants who meet the conditions defined]

Subject: Research Opportunity: Using your voice to improve the quality of the care you and other patients receive at NM Cancer Centers, and we are inviting you to participate!

Send test email

Paragraph B I [Rich Text Editor Icons]

**La versión en español está abajo**

Dear [patient\_firstname] [patient\_lastname],

I am writing to you about a research opportunity for patients currently receiving care in the Northwestern Medicine (NM) system. The NU IMPACT Study is working to improve the quality of the care you and other patients receive at NM Cancer Centers, and we are inviting you to participate!

**NOTE:** You may modify or remove any text you wish in the Compose Message text box above. Make sure you include either [survey-link] or [survey-url] in the text or else the participant will not have a way to take the survey.

**STEP 2: Conditions**

**Specify conditions for sending invitations:**

When the following survey is completed:  
 --- select a survey ---

AND

When the following logic becomes true:  
 [upload\_dt] <> "" and [gender] <> "" and [site] <> "" and [continuum] <> "" and datediff("today", [upload\_dt], "d")=0  
(e.g., [age] > 30 and [sex] = "1")

How do I use special functions?

Test logic with a record: -- select record --

Ensure logic is still true before sending invitation? [?](#)  
[How to use 'stop logic' to disable an automated invite](#)

**STEP 3: When to send invitations AFTER conditions are met**

Send immediately

Send on next -- select day -- at time [ ] [ ] AM

Send the invitation [0] days [2] hours [0] minutes  
 after [ ] the automated survey invitation has been triggered [ ] [?](#)

Send at exact date/time: [ ] [ ] M/D/Y H:MM

**OPTIONAL: Enable reminders**

Re-send invitation as a reminder if participant has not responded by a specified time? (Times below refer to AFTER original invitation time.)

Save Save & Copy to... Cancel

Research Opportunity: Using your voice to improve the quality of care for all Northwestern Medicine ca...

File Message Acrobat Tell me what you want to do...

Delete Reply Reply Forward All To Manager Team Email Move Move Assign Policy Categorize Follow Up Translate Zoom Send to OneNote

Fri 4/16/2021 12:32 PM

**NU IMPACT**

Research Opportunity: Using your voice to improve the quality of care for all Northwestern Medicine cancer patients [Oport

To: Nicola Lanck

Dear \_\_\_\_\_,

I am writing to you about a research opportunity for patients currently receiving care in the Northwestern Medicine (NM) system. The NU IMPACT Study is working to improve the quality of the care you and other patients receive at NM Cancer Centers, and we are inviting you to participate!

You are being contacted because you are a patient in a NM Cancer Center, are age 18 or older, you may have a current diagnosis or history of cancer, and your oncology care provider has agreed for their patients to be contacted for this project.

Participation in this study involves the completion of online study questionnaires (from a computer, smartphone, or other mobile device) over the next year:

- Study questionnaires are completed during a one-year period.
- Study questionnaires are emailed directly to you and can be completed using your computer or mobile device.
- For every study questionnaire you complete, you will be entered into a raffle for a chance to win a \$100 gift card. A raffle will occur every quarter (that is, every 3 months) and there will be 5 winners every quarter.
  - This means if you complete two study questionnaires within a quarter (3 months) your name will go into the raffle drawing twice.

If you would like to participate, simply click the NU IMPACT Study link provided below. It will take you to a protected website where you will be asked to review and sign a consent form and then to complete the first questionnaire. The consent form will provide detailed information about the study and how we plan to protect your privacy and the information you provide.

[Consent to Participate in NU IMPACT Study/Consentimiento para participar en el estudio NU IMPACT](#)

**PLEASE NOTE:** If you choose to participate, we ask that you please complete this first questionnaire within 3 days. You will receive your next questionnaire

# EDW Recruitment Lessons Learned

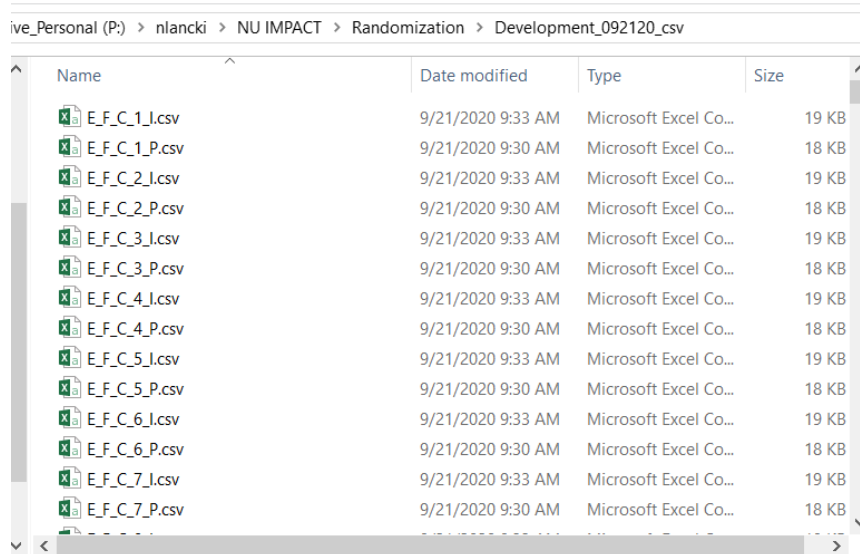
- Communication is important (weekly meetings with EDW analyst)
- Use a unique ID (EDW ir\_id) for REDCap Record ID to avoid issues with overwriting
- Be specific /detailed in query request
- Defining eligibility: list of ICD codes versus Grouper ID
- Recognize limitations of electronic health record for eligibility and be prepared to address any issues
- Test out on smaller scale and scale up
- EHR recruitment response rate can be low (10-11%)
- Importance of RA/project manager
- Expect the unexpected, and be ready to respond

# Randomization Considerations

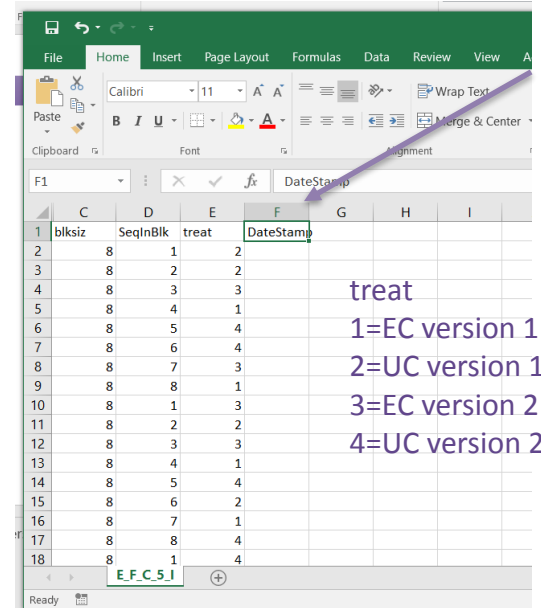
- Pre-Implementation: Randomization to survey version for “counterbalance”
- Post-Implementation: Randomization to survey version and intervention arm (Enhanced or Usual Care) stratified by:
  - Site (7 clinical units)
  - Gender (Male, Female)
  - Cancer Continuum (Curative, Non-curative, Survivorship)
  - Language Preference for study (English or Spanish)
- Sites transition from Pre to Post Implementation at different times
- Needed to communicate treatment assignment to Epic to control display of MyChart

# Randomization Allocation Tables

- Created allocation tables for each strata using statistical software
- Separate lists Pre-I and Post-I



E= English, F=Female, C=Curative, 5=Site 1, I=Post-Implementation



# Stage 1: Nightly recruitment/enrollment process (EDW -> REDCap)

## NU IMPACT Staging (Recruitment and Randomization)

### Criteria Field(s)

Consent::Consent Date

### Stratified Field(s)

EDW Data::Site

EDW Data::Gender

EDW Data::Cancer Continuum

Consent::Language

### Assignment Field(s)

Randomization:: UUID

Randomization:: assignment

Randomization:: date

### Legend

Input data

Output data

Processing code/program

C# program runs daily  
via Windows scheduled task

Allocation tables hosted on  
NU File server

## NU IMPACT

Registration:: Cancer Continuum

Registration:: Gender

Registration:: Site

Registration:: Language Preference

Registration:: UUID

Registration:: Treatment Arm

## NU IMPACT Spanish

Registration:: Cancer Continuum

Registration:: Gender

Registration:: Site

Registration:: Language Preference

Registration:: UUID

Registration:: Treatment Arm



# Follow-up Assessments (REDCap)

- Separate REDCap projects for follow-up of consented participants (English & Spanish)
- Follow-up consented/active participants (anyone who withdraws from study will not be contacted)
- Monthly survey-based assessments sent using REDCap ASI logic based on days from consent and if actively enrolled

Redcap Measures	BL	1	2	3	4	5	6	7	8	9	10	11	12
Monthly Screener*	x	x	x	x	x	x	x	x	x	x	X	X	X
Comprehensive Assessment**	x			x			x			x			x

\*PROMIS CATs (Pain, Fatigue, Physical Function, Anxiety, Depression), PRO CTCAE, Physical Health

\*\*Includes measures on Healthcare Utilization, Health Literacy, Financial Distress, Isolation, Communication, Self-efficacy, Support

# Roll out of clinics in steps/over time

- Clinic unit roll out order randomized
- Pre-Implementation data collection for 6 months, then switch to Post-Implementation
- Added form in REDCap (Configuration file) to track which sites go live when
  - Includes fields for dates started Pre and Post
  - Current status for each site (referenced by C# program)

The screenshot shows a REDCap data entry form titled "Current Status of Site". The form contains a table with the following structure:

		Pre-Implementation	Post-Implementation	Completed Recruitment	
Status Galter (Central)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	
Status Olson (Central)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Status Delnor (West)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset
Status ____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset

On the right side of the form, there are three buttons: "Save & Exit Form", "Save & Go To Next Form", and "-- Cancel --".

# REDCap → Study Tracker Interface

\*\* Study Tracker Interface with REDCap:

<https://www.nucats.northwestern.edu/resources/data-science-and-informatics/software-tools-development/redcap.html>

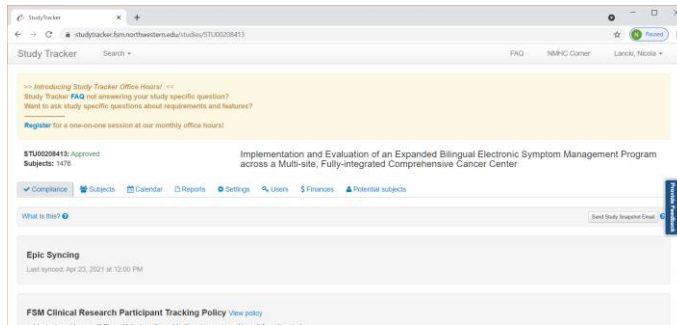
☑ I am interested in learning more about using REDCap for eConsent. How can I learn more?

A webinar recently took place on this topic and includes many details that are beneficial when considering the use of REDCap for eConsent. Learn the benefits of the eConsent Framework and Study Tracker push while obtaining some important tips and steps for setup. The webinar session is only available after logging in with your NU NetID and while on the VPN. The video is ~40 minutes in length.

You may access the video [here](#) .

# Study Tracker Interface and Epic Integration

- All clinical studies overseen by the NU IRB involving FSM faculty are required to record participants in Study Tracker
- Study tracker pushes information to Epic (hourly) for billing purposes (study billed for medical services for research not patient or their insurance)
- Utilized this infrastructure to integrate NU IMPACT randomization assignment into patient record to control an individual patients' MyChart Display for EC vs UC



MyChart Display of NMPRO scores over time (EC only)



## Stage 2: Nightly registration process (REDCap -> StudyTracker)

### NU IMPACT/Spanish

#### Criteria Field(s)

Consent::Consent Date

#### Stratified Field(s)

Registration::UUID

Registration::First Name

Registration::Last Name

Registration::DOB

Registration::Gender

Registration::MRN

Registration::Ethnicity

Registration::Race

Registration::Budget Arm

C# program runs daily  
via Windows scheduled task

Study Tracker API

Study Tracker

# REDCap: Data Entry Trigger

**Enable optional modules and customizations**

Optional

- Repeatable instruments [?](#)
- Auto-numbering for records [?](#)
- Scheduling module (longitudinal only) [?](#)
- Randomization module [?](#)
- Designate an email field for communications (including survey invitations and alerts) [?](#)



**Additional customizations**

- H Enable the Data History popup for all data collection instruments?**  
If enabled, an icon will appear next to every field on a data collection instrument. When the icon is clicked, the history of all data entered into that field for that record will be listed chronologically and will display all previous values, who changed the value at each instance, and the time it was changed.
- 📁 Enable the File Version History for 'File Upload' fields?**  
The File Version History allows you to maintain previous versions of a file for a File Upload field on a form or survey. If a new version of a file needs to be uploaded for the field, instead of deleting the current file before adding the new one, you may simply upload a new file (via the 'Upload new version' link), in which all older versions will be kept and will be accessible for viewing/download in the Data History popup for the field. This feature provides the convenience of accessing older versions of the file instead of having to delete them. (Note: Older versions of a file will not be accessible anywhere else in the project except the Data History popup. For instance, they will not be included in the zip file of all files uploaded for a given record or for the whole project.) Also, the Data History popup must be enabled (below) in order to use the File Version History.
- 🕒 Display the Today/Now button for all date and time fields on forms/surveys?**  
If enabled, a 'Today' button will be displayed to the right of all date fields, and a 'Now' button will be displayed to the right of all time, datetime, and datetime\_seconds fields. Clicking the button will automatically set the field's value with the current date or time.
- 📄 Require a 'reason' when making changes to existing records?**  
Require users to enter a reason (200 character max) in a text box when making any data changes to an already existing record on a data collection instrument. The prompt is triggered when clicking the Save button on the page. Any 'reasons' entered can then be viewed anytime afterward on the Logging page. Note: If the instrument does not yet have any data collected for it, then a reason will not be required (this includes importing data via the Data Import Tool). This feature is only triggered when adding, editing, or deleting data for an instrument that contains previously-collected data for one or more fields on the instrument.
- 🔗 Data Entry Trigger**  
The Data Entry Trigger is an advanced feature. It provides a way for REDCap to trigger a call to a remote web address (URL), in which it will send a HTTP POST request to the specified URL whenever \*any\* record or survey response has been created or modified on \*any\* data collection instrument or survey in this project (it is \*not\* triggered by data imports - including API imports and Mobile App imports - but only by normal data entry on surveys and data entry forms). Its main purpose is for notifying other remote systems outside REDCap at the very moment a record/response is created or modified, whose purpose may be to trigger some kind of action by the remote website, such as making a call to the REDCap API. [View more details](#)

URL of website:

Example: [https://www.mywebsite.com/redcap\\_trigger\\_receive/](https://www.mywebsite.com/redcap_trigger_receive/)

Example: </det/index.php>

# Randomization/Epic integration Lessons Learned

- Consider other competing project work/resources when determining a timeframe
- We were able to test in a development environment, but more difficult to test when live in Epic
- Rely on communication with study RA/staff/etc

# Questions?

Email:

[nicola.lancki1@northwestern.edu](mailto:nicola.lancki1@northwestern.edu)

[michael-bass@northwestern.edu](mailto:michael-bass@northwestern.edu)