

Increase EDC's Efficiency, Ease of Use Through End-to-end Trial Designer



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Introducing Open Source Tool

- Business Objectives
- Design Principles
- Proposed UI
- Backend Integration
- Roadmap
- Looking for Collaborators

End-to-end Trial Design Tool

- Accelerate Clinical Trials
- Faster Study Design
- Analyze Early and Often

The Problem we Solve

- Web-based
- Easy to use
- EDC-agnostic
- Integrated with Synthetic Data generator
- Ingest Rave's ALS directly

Simple

- Suitable for non-technical users

Integrated

- One tool to control many others

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Libraries Forms Studies Patient Journeys Build UAT Analytics

[Add New Library](#)

Library Name	Library ID	Last Version	Last Update	Updated By	Actions
Cardiovascular	CV	CV01	2022/10/01	Mike Michaels	Edit View Studies using Library
Immunology	IM	IM02	2022/10/01	Mike Michaels	Edit View Studies using Library
Infectious	IN	IN03	2022/10/01	Mike Michaels	Edit View Studies using Library
Neuroscience	NE	NE04	2022/10/01	Mike Michaels	Edit View Studies using Library
Oncology	ON	ON02	2022/10/01	Mike Michaels	Edit View Studies using Library
Retinal	RE	RE01	2022/10/01	Mike Michaels	Edit View Studies using Library
Vaccine	VA	VA05	2022/10/01	Mike Michaels	Edit View Studies using Library

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Metadata Management

- Manage, edit, analyze, and build libraries from simple UI
- Reduce time to publish new releases
- Web app to avoid system compatibility issues
- Manage different roles, users

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Libraries Forms Studies Patient Journeys Build UAT Analytics

Select Library **Oncology** Select Version **ON02** [Add New Form](#)

Name	Form Description	Actions
AE	An events domain that contains data describing untoward medical occurrences in a ..	Edit View Studies
AG	An interventions domain that contains the agents administered to the subject as part ..	Edit View Studies
CE	An events domain that contains clinical events of interest that would not be classified ..	Edit View Studies
CM	An interventions domain that contains concomitant and prior medications used by the..	Edit View Studies
CO	A special-purpose domain that contains comments that may be collected alongside ..	Edit View Studies
DA	A findings domain that contains the accountability of study drug, such as information ..	Edit View Studies
DD	A findings domain that contains the diagnosis of the cause of death for a subject.	Edit View Studies
DM	A special-purpose domain that includes a set of essential standard variables that ..	Edit View Studies
DS	An events domain that contains information encompassing and representing data ..	Edit View Studies
DV	An events domain that contains protocol violations and deviations during the course ..	Edit View Studies
EC	An interventions domain that contains information about protocol-specified study ..	Edit View Studies
EG	A findings domain that contains ECG data, including position of the subject, method ..	Edit View Studies

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EDC-less Form Design

- Manage, edit, analyze each library's forms in one page
- Linkages to individual Studies using each Form
- Fast switching between library versions
- View Forms as they'd look like in the chosen EDC

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Libraries Forms Studies Patient Journeys Build UAT Analytics

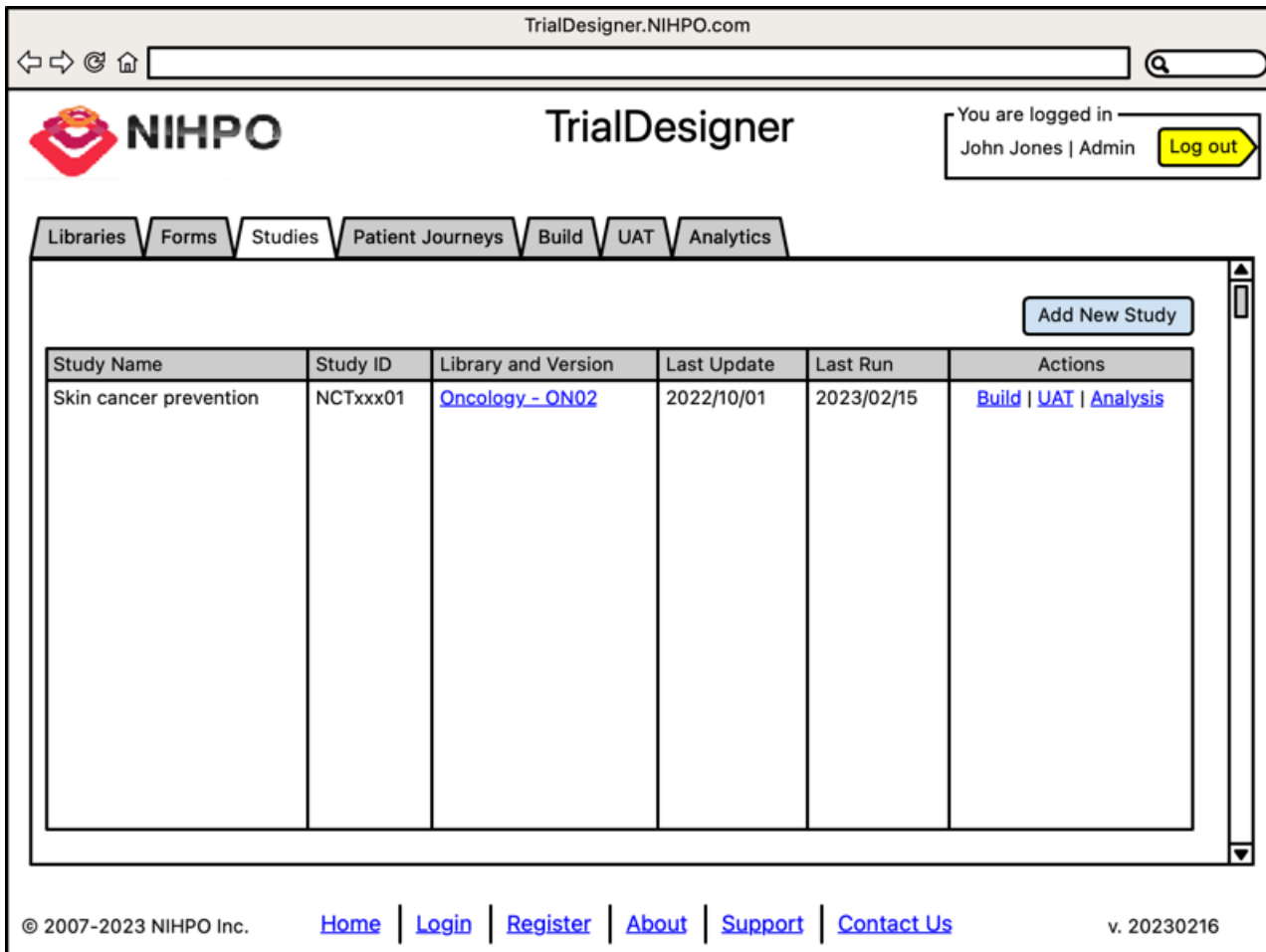
Edit Form DM Select Version CDASHIG v2.2 [Save Form](#)

Order	Variable	Variable Label	Prompt	Type	Core	Target
1	STUDYID	Study Identifier	Protocol/Study	Char	HR	STUDYID
2	SITEID	Study Site Identifier	Site (Identifier)	Char	HR	SITEID
3	SUBJID	Subject Identifier for the Study	Subject/Participant (Identifier)	Char	HR	SUBJID
4	BRTHDAT	Birth Date	Birth Date	Char	R/C	BRTHDTC
5	BRHTIM	Birth Time	Birth Time	Char	O	BRHTDTC
6	AGE	Age	Age	Num	O	AGE
7	AGEU	Age Units	Age Unit	Char	O	AGEU
8	DMDAT	Demographics Collection Date	Collection Date	Char	R/C	DMDTC
9	SEX	Sex	Sex	Char	R/C	SEX
10	ETHNIC	Ethnicity	Ethnicity	Char	O	ETHNIC
11	CETHNIC	Collected Ethnicity	Ethnicity	Char	O	QVAL
12	RACE	Race	Race	Char	R/C	RACE
13	CRACE	Collected Race	Race	Char	R/C	QVAL

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Web-based Form Editing

- Create or modify fields in real time
- Access CDASH and SDTM guidelines for assistance

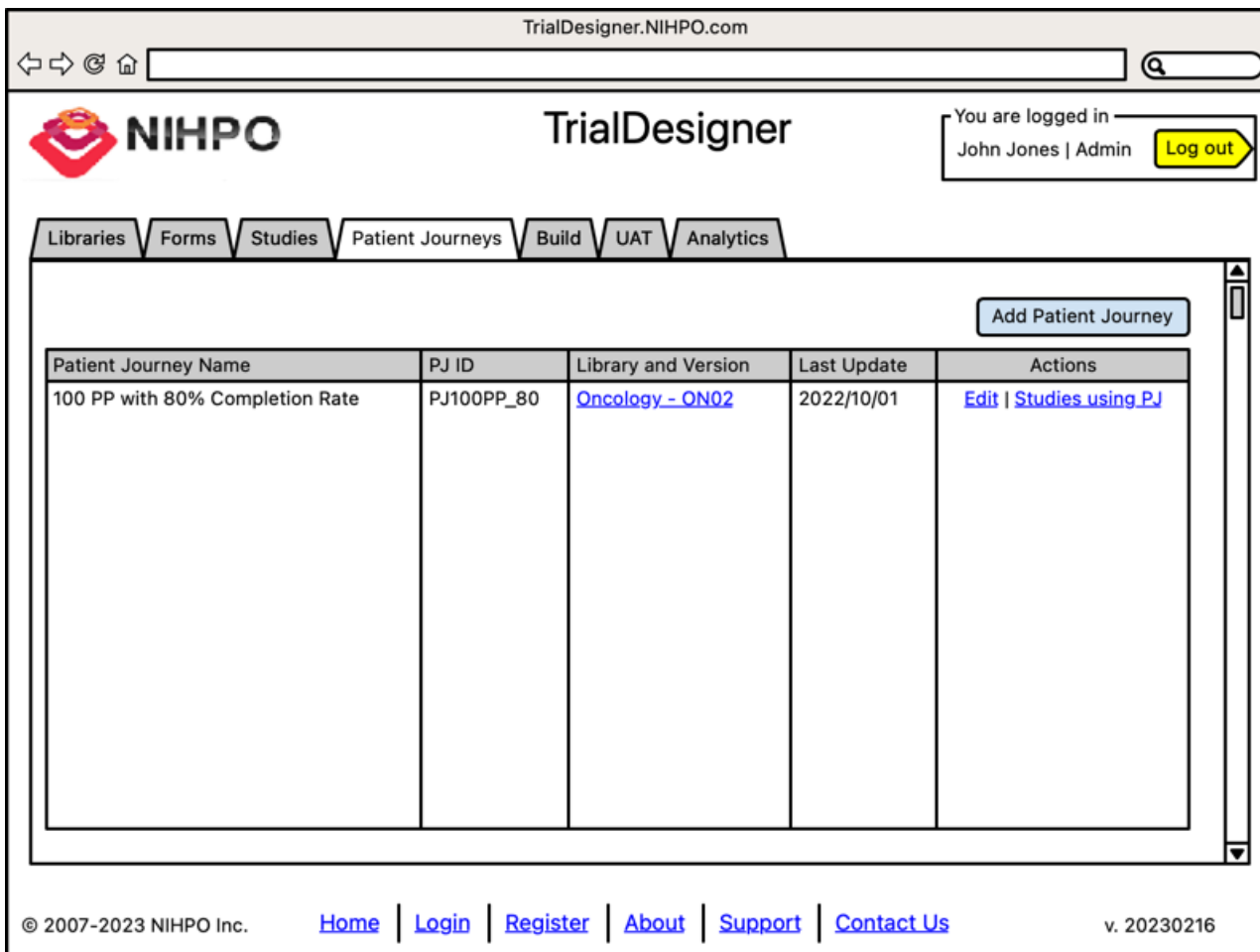


The screenshot shows the TrialDesigner.NIHPO.com web application. The browser address bar displays "TrialDesigner.NIHPO.com". The page header includes the NIHPO logo, the "TrialDesigner" title, and a user login status: "You are logged in John Jones | Admin" with a "Log out" button. Below the header is a navigation bar with tabs: "Libraries", "Forms", "Studies", "Patient Journeys", "Build", "UAT", and "Analytics". The "Studies" tab is active. A table lists studies, with one study visible: "Skin cancer prevention" (Study ID: NCTxxx01, Library and Version: [Oncology - ON02](#), Last Update: 2022/10/01, Last Run: 2023/02/15). The "Actions" column for this study contains links: [Build](#) | [UAT](#) | [Analysis](#). An "Add New Study" button is located above the table. The footer contains copyright information: "© 2007-2023 NIHPO Inc.", navigation links: [Home](#) | [Login](#) | [Register](#) | [About](#) | [Support](#) | [Contact Us](#), and the version number: "v. 20230216".

Study Name	Study ID	Library and Version	Last Update	Last Run	Actions
Skin cancer prevention	NCTxxx01	Oncology - ON02	2022/10/01	2023/02/15	Build UAT Analysis

Build, Load Data, Test

- Build study in chosen EDC
- Load study-specific synthetic Data
- Execute User Acceptance Testing (“UAT”) in chosen EDC with pre-loaded Synthetic Data
- Automatic analysis of study: metadata and expected data



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Libraries Forms Studies Patient Journeys Build UAT Analytics

Add Patient Journey

Patient Journey Name	PJ ID	Library and Version	Last Update	Actions
100 PP with 80% Completion Rate	PJ100PP_80	Oncology - ON02	2022/10/01	Edit Studies using PJ

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Define Arms, Visits

- Manage, edit and analyze every Patient Journey (“PJ”)
- Re-use typical PJs across multiple studies
- Create your specific PJ and replicate on demand

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The Patient is:

☒ Screened
☐ Not screened

If not screened —

Reason

What is AE toxicity? What is the AE outcome?

☒ 0
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5

☒ Not recovered / Not resolved
☐ Fatal
☐ Recovered / Resolved

Is there Concomitant Medication (CM)?

☒ Yes
☐ No

[Add Patient Journey](#)

If screened —

They are:

☒ Discontinued from treatment
☐ Discontinued from treatment and trial
☐ Completed

Treatment discontinuation reason

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Customize Subjects' Path

- Specify:
 - screen failures
 - treatment discontinuation
 - trial discontinuation reasons
- Specify Adverse Events properties

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Study Name	Study ID	Library and Version	Patient Journey	EDC	Load Test Data	Actions
Skin cancer prevention	NCTxxx01	Oncology - QN02	PJ100PP_80	Classic Rave	Y	>> Run

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Study Build in Hours

- Build your study in the preferred EDC
- Use NIHPO's Open Source Synthetic Health Data generator to fully test trial

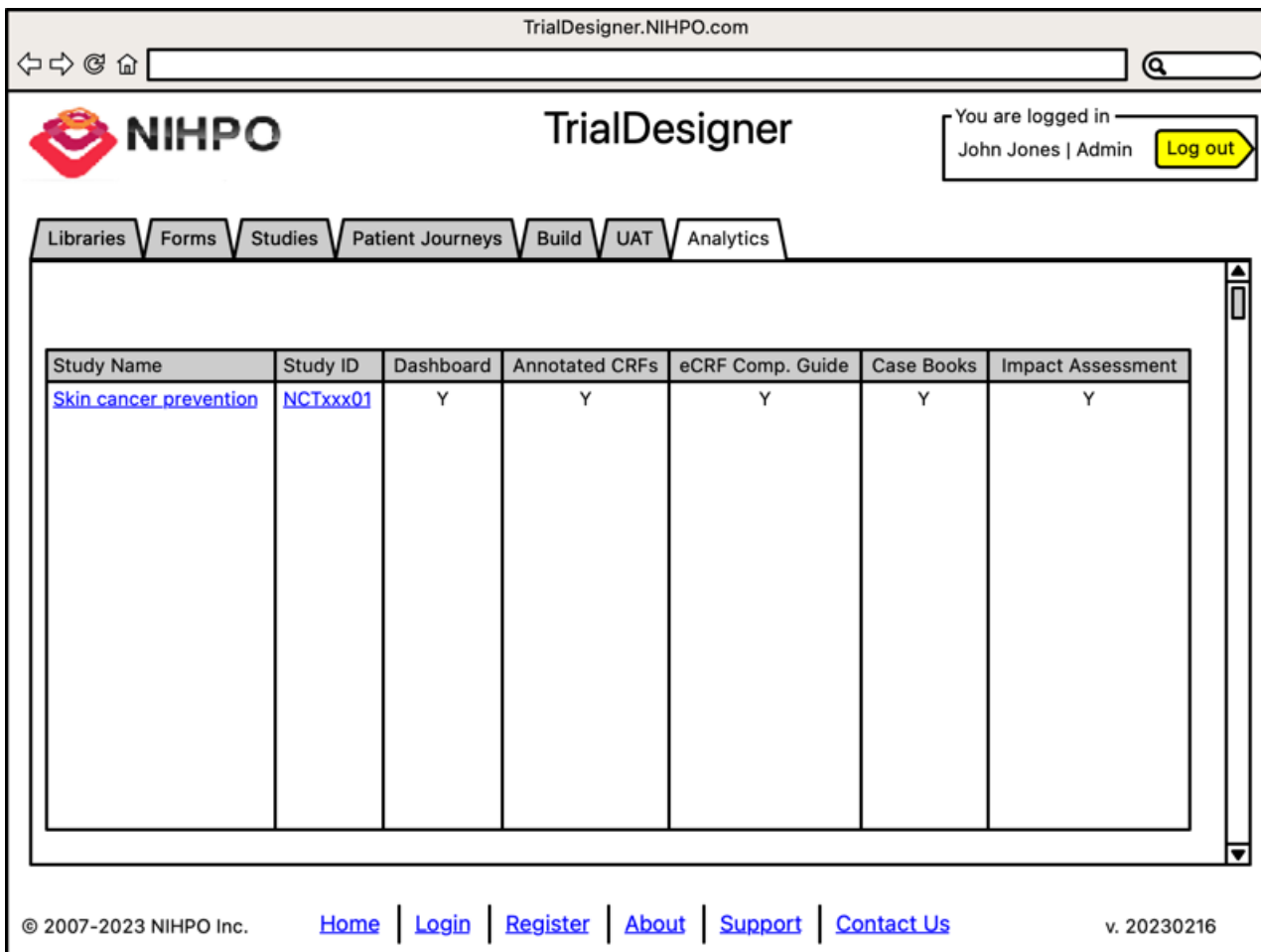
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Study Name	Study ID	Library and Version	EDC	Generate Report	Generate Videos	Actions
Skin cancer prevention	NCTxxx01	Oncology - QN02	Classic Rave	Y	Y	>> Run

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Test Early, Test Often

- Automatically generate User Acceptance Testing with Synthetic Health Data
- Generate several reports showing errors and possible improvements in study's ALS
- Video recording of Robotic Process Automation ("RPA")



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Libraries Forms Studies Patient Journeys Build UAT Analytics

Study Name	Study ID	Dashboard	Annotated CRFs	eCRF Comp. Guide	Case Books	Impact Assessment
Skin cancer prevention	NCTxxx01	Y	Y	Y	Y	Y

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Analyze Before FPI

- Automatically generate analytics reports:
 - Dashboards
 - Annotated CRFs
 - eCRF Completion Guide
 - Case Books
- Generate Impact Assessment between previous and current release of studies/libraries

PHUSE Open Data Repository

- Generates realistic, scientifically-accurate Synthetic Health Data
- Free Docker container available now
- Free account at <https://Portal.NIHPO.com>

Enterprise-grade Features (Future)

- Integration with Metadata Management (NIHPO's Version Control System)
- Role Management, with enhanced security and access controls
- Private hosting
- Multiple EDC connections beyond Rave

Ingest ALS	Now
Build study in Rave	Now
Generate ALS-specific Synthetic Health Data	Now
Generate Impact Assessment	Now

Fund or Provide Requirements

- Sponsors
- CROs
- Regulators

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