

REDCap @ Charité & BIH

Ein Blick zurück ...

2. Oktober 2020

Peter Brunecker

Charité GB IT / BIH Core Facility IT

Eine kurze (Entstehungs-)Geschichte von REDCap



HIPAA (U.S. Health Insurance Portability and Accountability Act), schreibt vor, dass alle Unternehmen im Gesundheitswesen strikte Regeln einhalten, die entwickelt wurden, um die Vertraulichkeit und Integrität von Patientendaten zu schützen.

1996



Vanderbilt University
(Nashville, TN)
Befund: Forscher verwenden weiterhin ungeeignete Methoden um Daten in ihren Forschungsprojekten zu verwalten

2004



Zunächst lokal für die eigenen Bedürfnisse der Vanderbilt University entwickelt, wird REDCap seit **2006** auch über ein Konsortium an Partner weitergegeben.

2006

REDCap 3

- Shared library
- API

REDCap 4

- Data Quality
- Randomization

Participant ID PPCR-001-1-00001

Data Collection Instrument	Pre-treatment (1)	Treatment (2)	Follow-Up 1 (3)	Follow-Up 2 (4)	Follow-Up 3 (5)
Demographic: Baseline					
Primary Diagnosis					
Baseline Health Inventory					
Tumor-related Surgery					
Imaging					
Radiation					
Chemotherapy And Protocols					
Follow Up					
Off-Study					
Radiation Prior To Proton Therapy					

Legend for status icons:
 Incomplete
 Unverified
 Complete

Kasper et al. (2014) The Pediatric Proton Consortium Registry: A Multi-institutional Collaboration in U.S. Proton Centers. *Int J Particle Ther*
DOI10.14338/IJPT.13-00006.1

Entwicklung des EDC-Systems ALMANACH am Centrum für Schlaganfallforschung Berlin (CSB)

ALMANACH - Windows Internet Explorer bereitgestellt von Charité-Intranet-Seite

ALMANACH

Client: 000

Case: blubb Title: NIHSS vor Intervention

Status: uncaptured Disable validation: ☐

Comment:

mRS Datum ☐ SDV mRS ☐ SDV

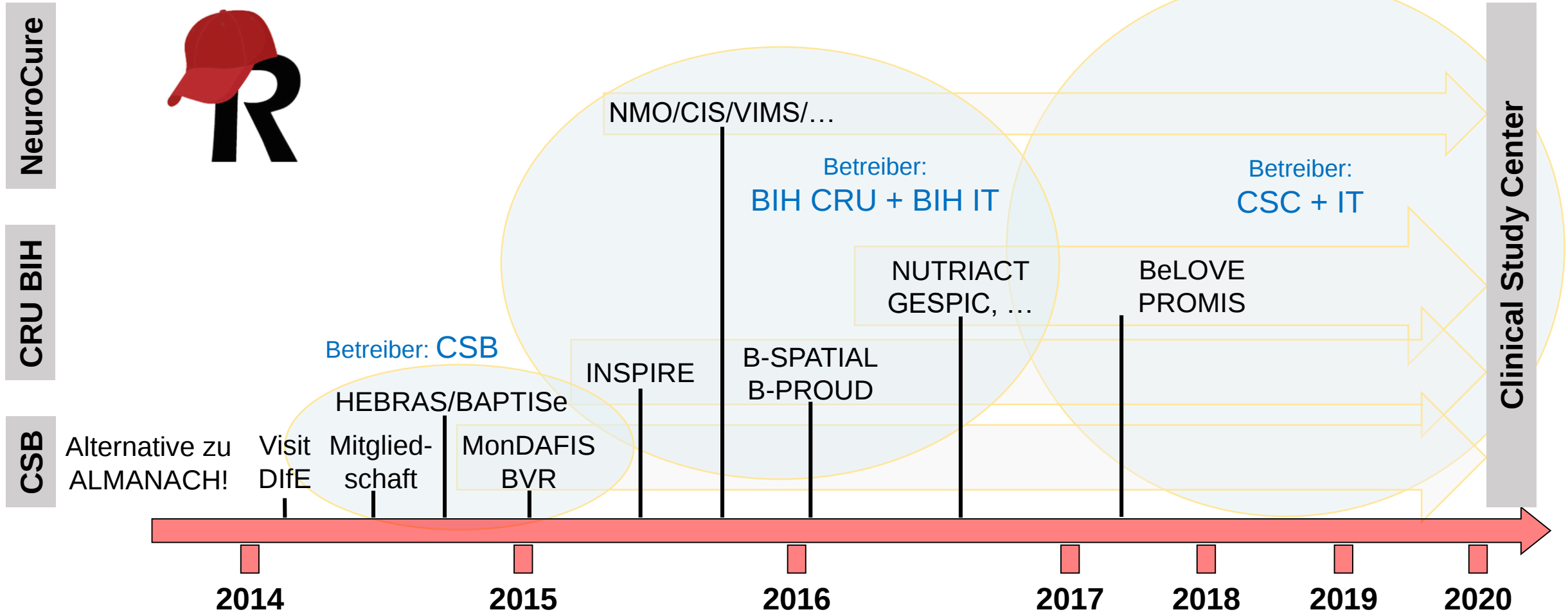
NIHSS Datum ☐ SDV NIHSS ges. ☐ SDV

Barthel Index Datum ☐ SDV Barthel Index ges. ☐ SDV

- Entwicklungszeitraum: 2009-2013
- basierte auf SAP Netweaver
- wurde entwickelt aufgrund spezifischer Anforderungen des CSB:
 - sehr große Zahl an Beobachtungsstudien
 - dadurch hohe prognostizierte Kosten bei Nutzung damals gängiger Studiensoftware
 - Mehrfachnutzung von klinischen Parametern in mehreren Studien und Registern
- Key features
 - Daten können in mehreren Studien gleichzeitig verwendet werden
 - browserbasiert
 - integrierter Studien-Designer
 - Plausibilitätskontrollen

REDCap an Charité/BIH

2013: Alternative zu ALMANACH gesucht



REDCap 5

- Multiple surveys per project
- Project Templates
- Real-time execution of Data Quality
- **Field Comment Log & Data Resolution Workflow**
- **Piping**
- **User Roles**
- OpenID und AWS S3
- Data Dictionary "Codebook" display

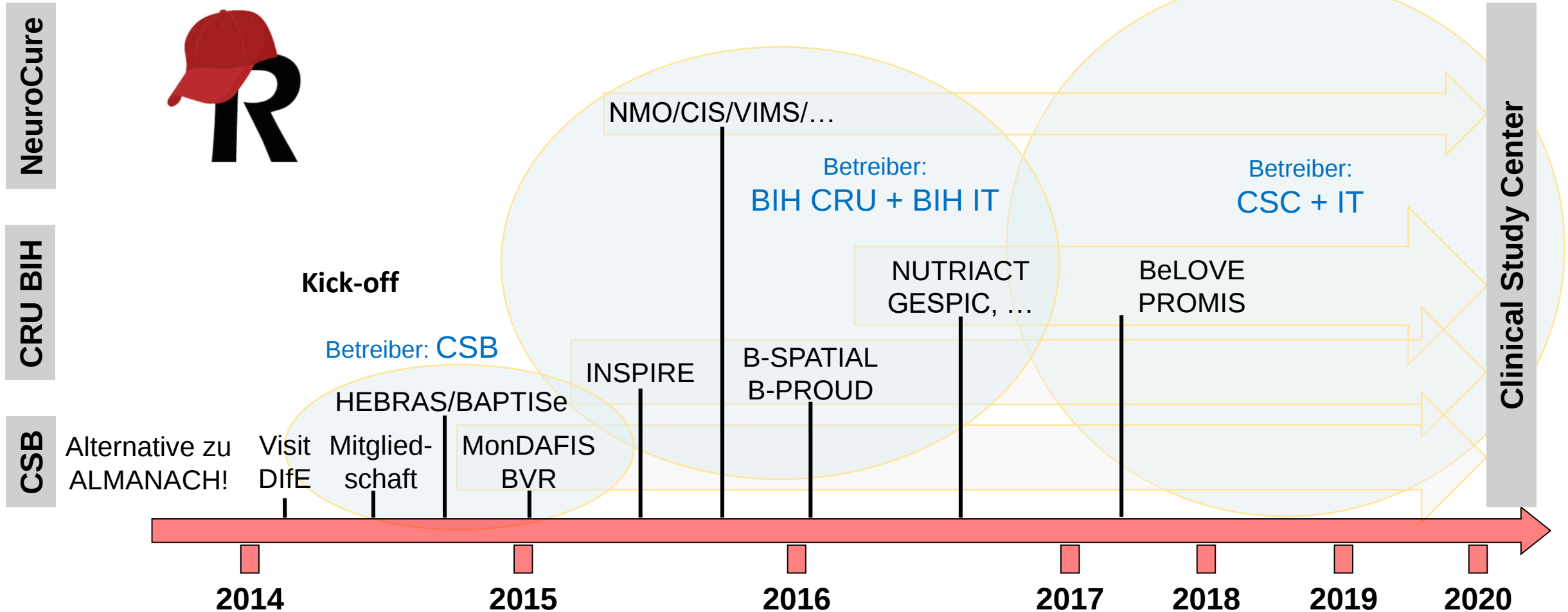
- Data Dictionary "Codebook" display
- Dynamic Data Pull (DDP)
- Survey Queue
- **Hooks**
- CATs from PROMIS

REDCap 6

- **Data Exports, Reports, and Stats**
- Survey Access Code, Survey Login and Short Code for survey
- Signature field
- **Auto-calculations when importing data**

REDCap an Charité/BIH

Kick-off für REDCap am CSB



MonDAFIS-Studie (ab 2014): Entwicklung von REDCap-Erweiterungen für das ID-Management

Enrollment (plugin)

New Patient

Please enter the following information about the patient.

Note: This information is used to avoid double enrollment and to contact patients later for follow-up interviews.

Lastname
 Firstname
☒ male ☐ female
 Date of Birth (DD.MM.YYYY)

Are the inclusion and exclusion criteria fulfilled?

☒ Yes ☐ No

Is there a signed informed consent form?

☒ Yes ☐ No

Patient successfully registered

The patient was successfully enrolled in the study under ID **[08002]**.

Please complete the [contact details](#) or start [collecting data](#).

Administration (hook)

No History, Field Comment Log or Data Resolution Workflow!

Editing existing Record ID **08002**

Event Name: **Inclusion**

Record ID: 08002
To rename the record, see the record action drop-down at top of the [Record Home Page](#).

Master data (read only)

This person master data can only be changed by the trustee and is NOT stored in REDCap. The information stored there is only displayed here.

Firstname: **E-PIX** John
Lastname: **E-PIX** Doe
Gender: ☒ male ☐ female
Date of birth: **E-PIX** 11.12.1999

Contact details

Contact details can be edited by the study team. Like the master data, they are NOT stored in REDCap.

Street and number: **E-PIX** 1196 Washington Avenue
Place: **E-PIX**
ZIP Code: **E-PIX**

Phone number and additional contact information: **E-PIX** (254) 584-3451
Expand
Example: (123) 456-7890 (not on weekends)

Form Status

Complete? ☒ Complete

No real content in the REDCap database!

Supporting

- Pre-Screening
- Enrollment (Study ID)
- Contact details administration



Trusted Third Party extensions

ab 2017 auch genutzt in



**MonDAFIS Trial
AF Registry**



BeLOVE cohort
*Berlin Longterm
Observation of
Vascular Events*

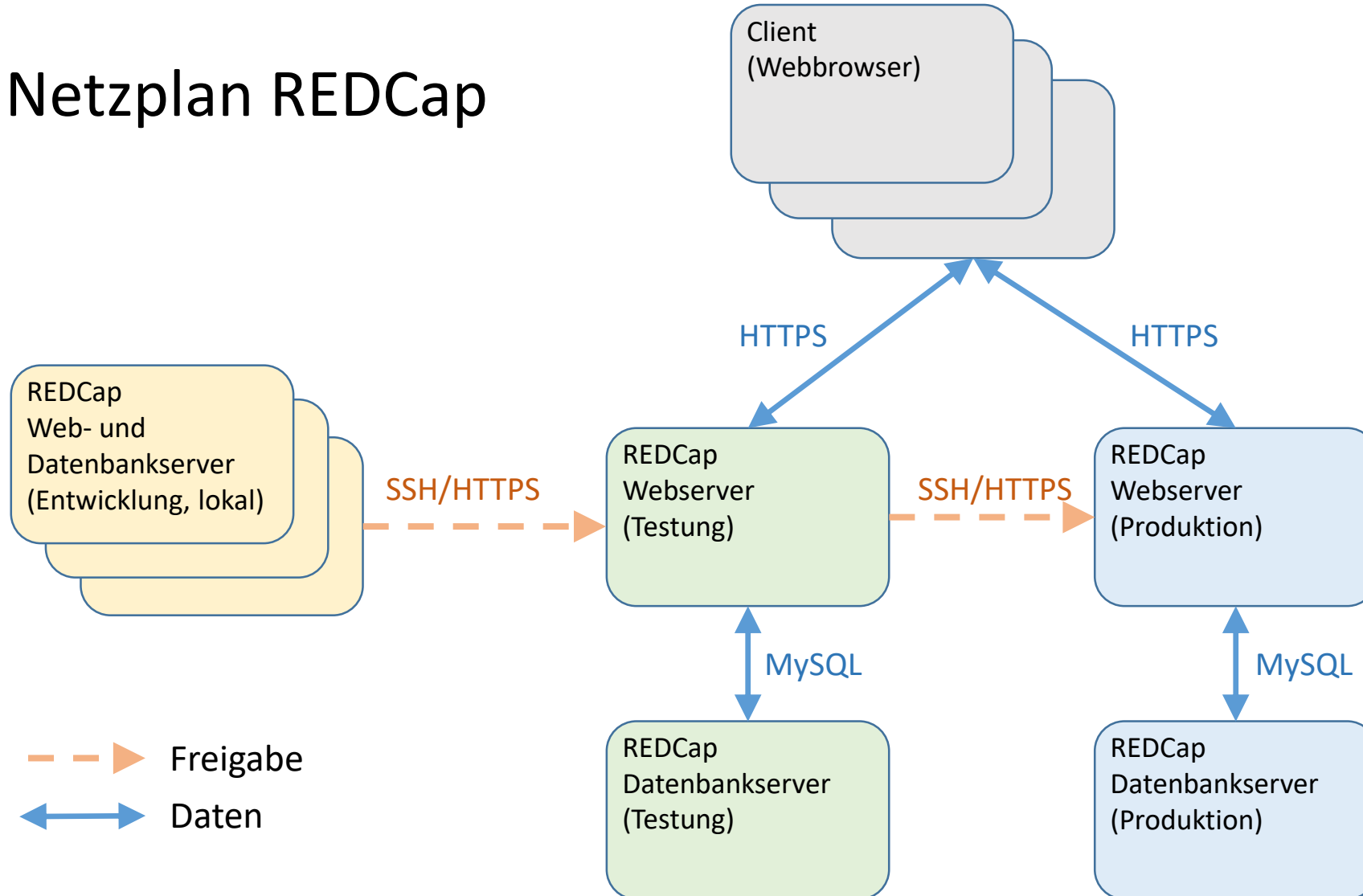


Powered by MOSAIC, Institute for
Community Medicine, University
Medicine Greifswald

<https://www.schlaganfallzentrum.de/forschung/ausgewaehlte-projekte/mondafis/>
<https://www.bihealth.org/de/forschung/projekte/belove>

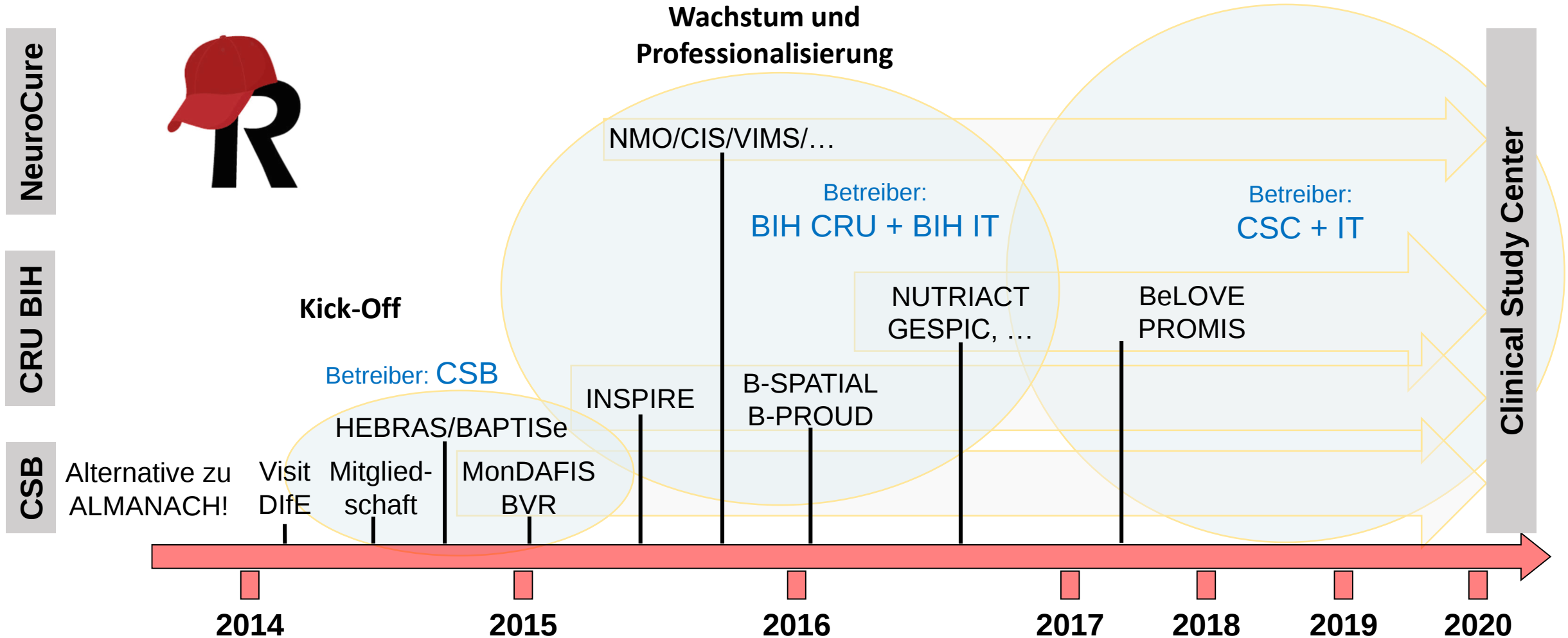
Brunecker, Mallach: Privacy-preserving data collection in REDCap: A European perspective. REDCapCon 2018

Netzplan REDCap

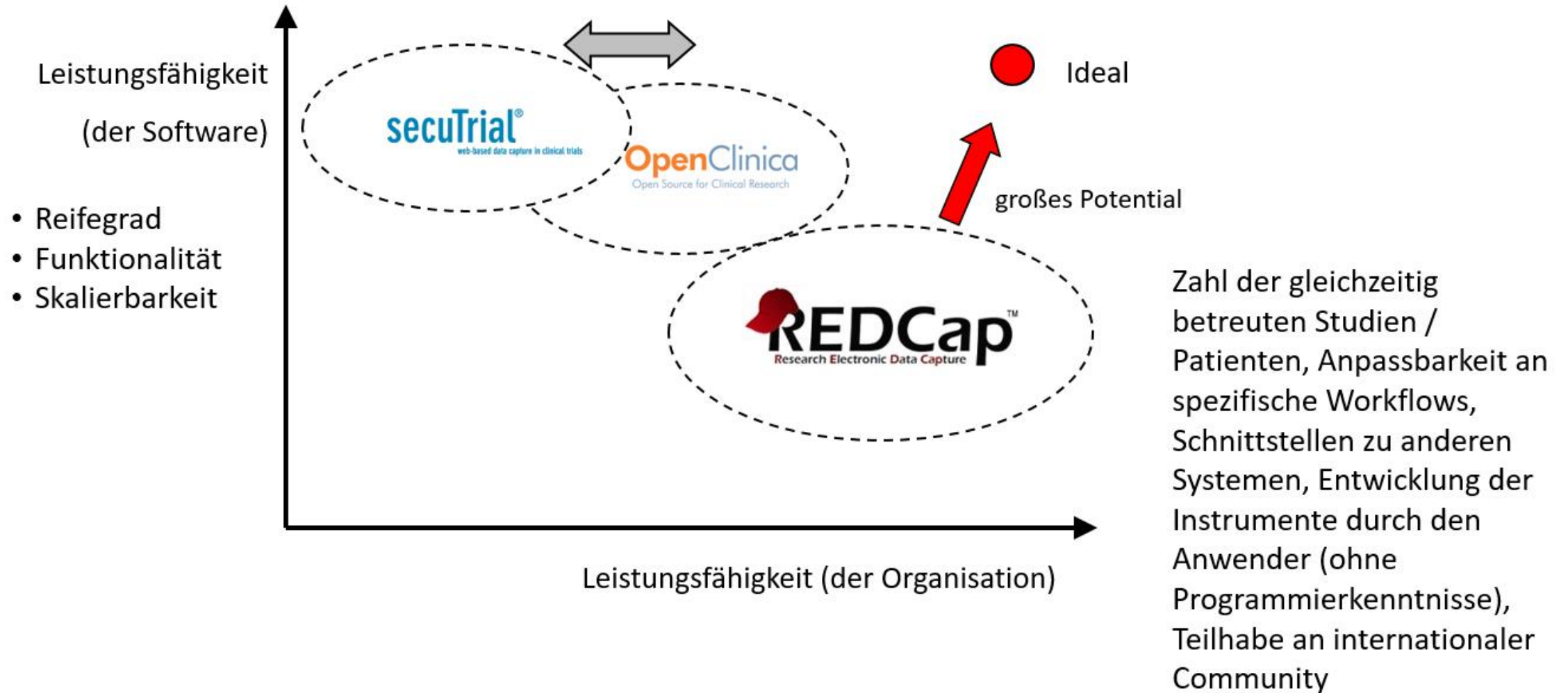


REDCap an Charité/BIH

Wachstum und Professionalisierung



2015: Strategieentscheidung pro REDCap für die BIH Clinical Research Unit (CRU)



REDCap 6 (2015)

- REDCap Mobile App for iOS and Android
- Twilio services
- Text-to-speech
- **Action Tags**
- SQL and ontology fields
- Two-factor Authentication
- API Playground
- Project Folders
- Survey themes
- Secure MySQL connections (SSL/TLS)

Carrier 9:31 AM 100%



Who is REDCap Mobile App's Audience?
[View](#)

Create New App User
Why create two users?
[View](#)

Create Admin	Create Data Collector
Admin Username: admin	First Username:
6-digit Admin PIN: 	6-digit PIN:
Re-enter 6-digit Admin PIN: 	Re-enter 6-digit PIN:
Suggest Random Password	Suggest Random Password

- CDISC ODM support
- Live filters in reports
- Admin Todo List
- Enhanced controls in surveys
- Account Manager user type
- Lots of new API methods

Data Collection Instrument

	Preliminary (#1)	(#2)	(#3)	Daily
Preliminary Survey (survey)	☒	☐	☐	
Mood (survey)	☐	☒	☐	☒
Diet (survey)	☐	☐	☐	☐
Caffeine Intake (survey)	☐	☐	☐	☒
Exercise (survey)	☐	☐	☐	☐
Delete all data on event:	☒	☒		

Repeating Instruments

Mood Caffeine Intake

Caffeine Intake

Daily

1	☒
2	☒

+ Add new

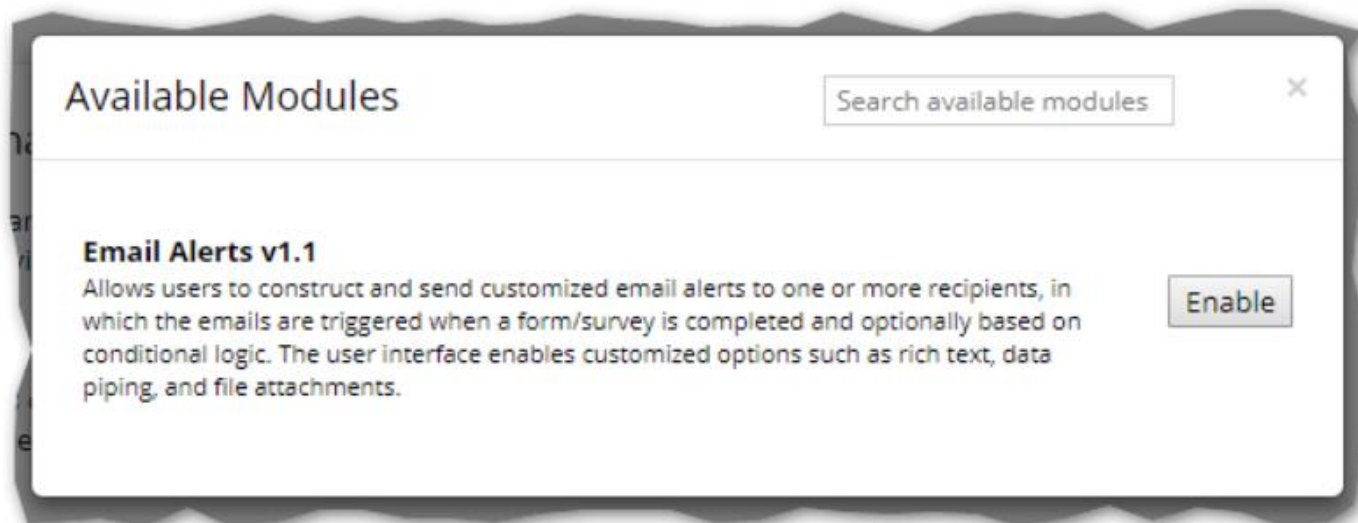
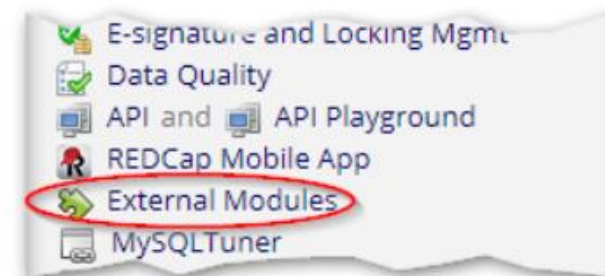
REDCap 7

- Repeating Instruments and Events

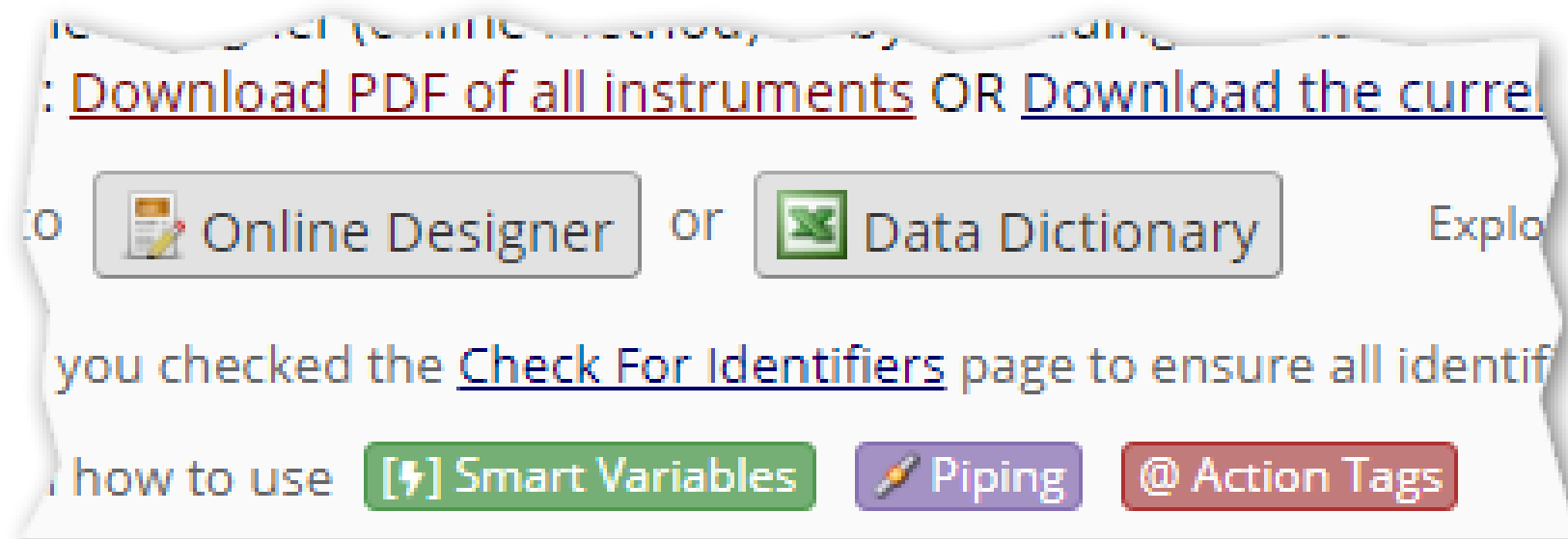
- Custom Record Status Dashboards
- REDCap Messenger

REDCap 8

- External Modules



- Sponsor Dashboard
- PDF Auto-Archiver & e-Consent Framework
- **Smart Variables**
- DDP on FHIR with EHR Launch
- Easy Upgrade
- Azure Blob
- Report Folders
- GDPR-related changes

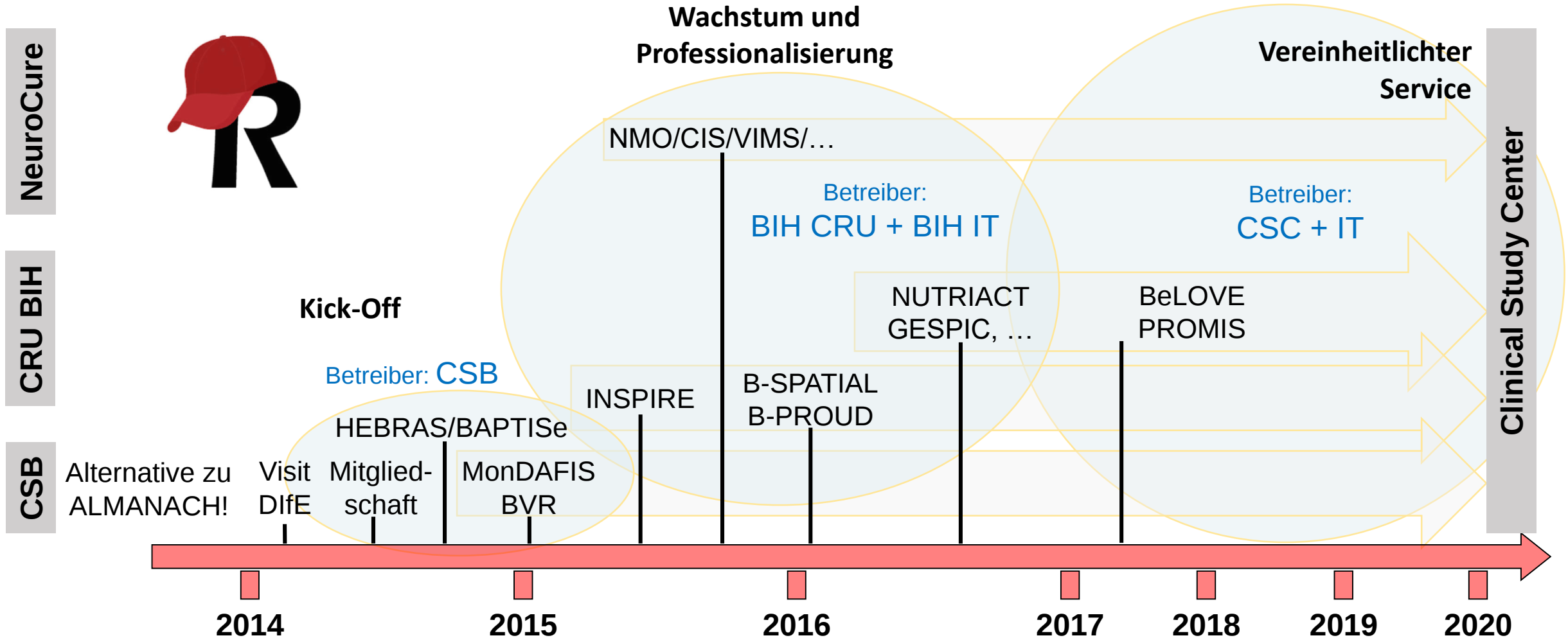


REDCap 9

- Alerts & Notifications
- Clinical Data Mart
- File Version History for File Upload fields
- Missing Data Codes
- SMS and Voice Calls for Alerts & Notifications (Twilio)

The screenshot shows the 'My Alerts' tab in the REDCap interface. At the top, there are tabs for 'My Alerts' and 'Notification Log'. Below them is a green button labeled '+ Add New Alert' and a checkbox for 'Show deactivated alerts'. A search bar is also present. The main area displays 'Alert #1: Data Modification Alert' with options to 'Edit' or 'Options'. The alert description states: 'When the instrument "Pseudonym [Any event]" is saved and has any form status.' Below this, there are buttons for 'Send immediately' and 'Send one time'. An 'Activity' section shows 'No alerts sent yet'. On the right, there is a 'Preview' section for an email notification, showing the 'To' field as 'peter.brunecker@charite.de', the 'Subject' as 'Data Change', and the 'Message' field.

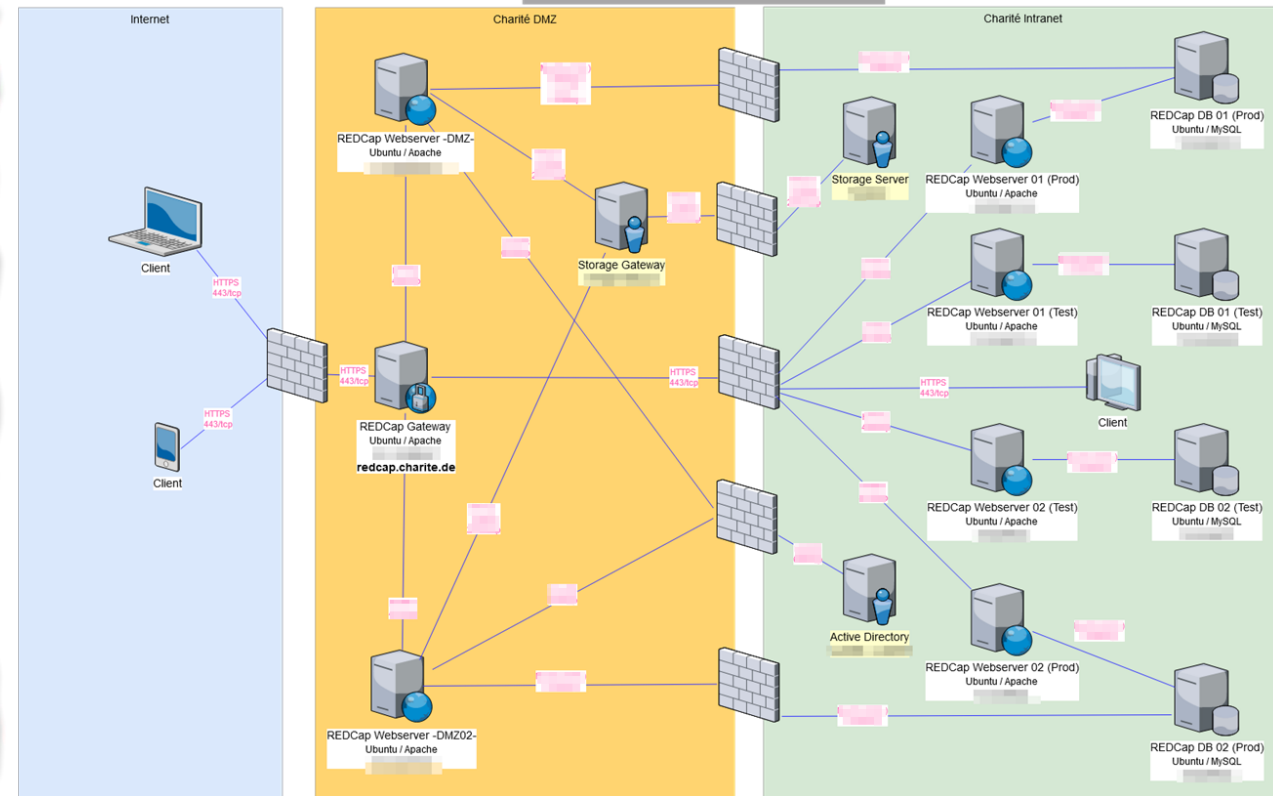
The screenshot shows a survey form with a green background. At the top, there is a blue header bar. Below it, there is a grey bar with the number '3'. The main content area has two radio buttons labeled 'Yes' and 'No'. Below these, there is a blue button labeled 'M' with a red circle around it. To the right of this button is a 'reset' link. Below the radio buttons, there is a blue bar with the text 'Not applicable (NA)'. At the bottom of the form, there is a yellow bar. Below the yellow bar, there is a grey bar with the numbers '2', '3 Neutral', '4', and '5 Love it'.



REDCap @ Charité / BIH (2020)

Service und Infrastruktur

REDCap Netzplan (Firewall-/Client-Sicht) - DRAFT -





CHARITÉ
UNIVERSITÄTSMEDIZIN BERLIN

Clinical Study Center



REDCap

Research Electronic Data
building and managing data

- Was ist REDCap?
- REDCap Workshops @
- REDCap User-Treffen
- Eine Studie mit REDCap
- Datenaustausch mit
- Beispiel-Studien an d

Leistungen

zurück

REDCap

COVID-19

Karriere

Über das CSC

Netzwerk

Google Durchsuchen Sie diese Website

Startseite > Leistungen > Services CTO > Data Services > REDCap

https://studycenter.charite.de/leistungen/services_cto/data_services/redcap/

- “View Project As...” feature (impersonate)

REDCap 10

- **Field Embedding**
- Granular administrator privileges
- To be continued ...

