



# Mobile Health Technology in Clinical Trial Nestlé Experience

2015-11-10

- Objective:
  - Evaluate the effect of combined Nutrition and Physical activity intervention on specific parameters
- Country: China
- Population: Elderly
- Around 50 Subjects
- How:
  - Typical Clinical Trial
  - Health Economics assessment through Clinical Outcome Assessment
  - Follow up of activity through activity tracker
- Opportunity:
  - Use a BYOD model to deliver electronic Clinical Outcome Assessment
  - Replace Activity Tracker with a marketed connected activity tracker



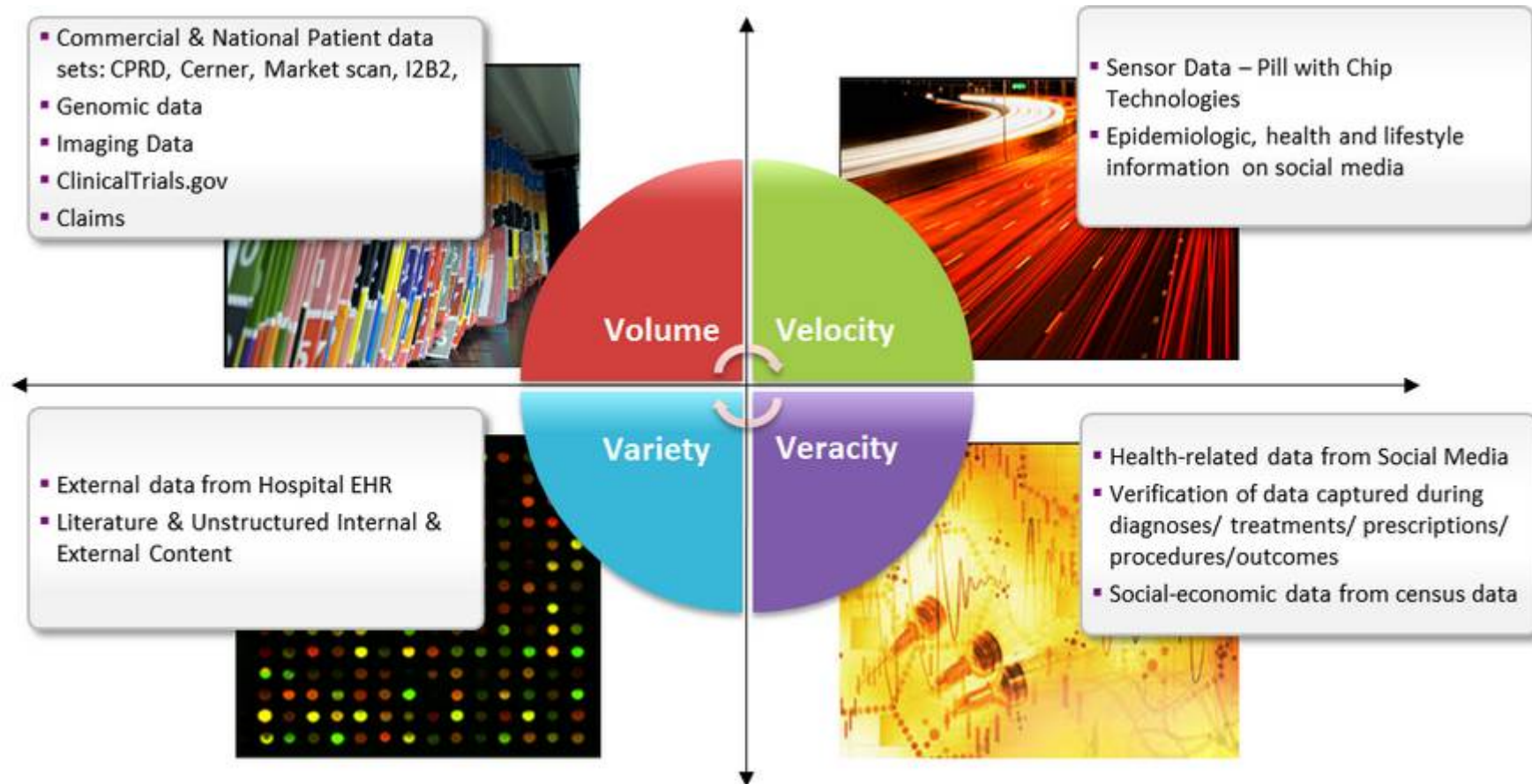
- What are the Data Source?
- How can we assure Data Protection?
- How can we treat large quantity of data?
- How can we ensure data traceability and trustability?
- How to ensure subject compliance and be proactive as a Sponsor?
- How can we correlate data together?

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How mHealth Clinical Trial compare to Big Data problematics

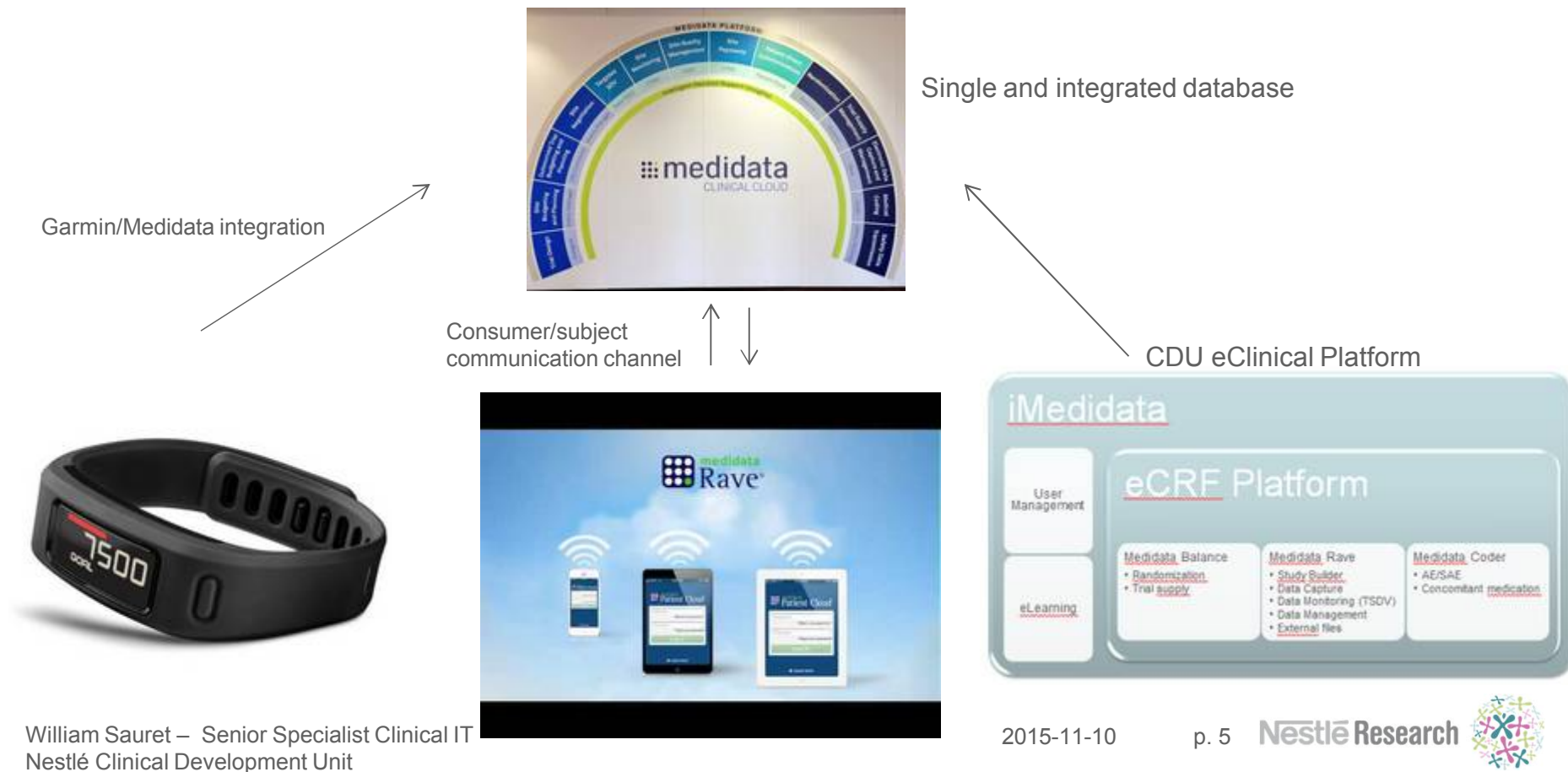
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# mHealth Clinical Trial vs «Big Data»



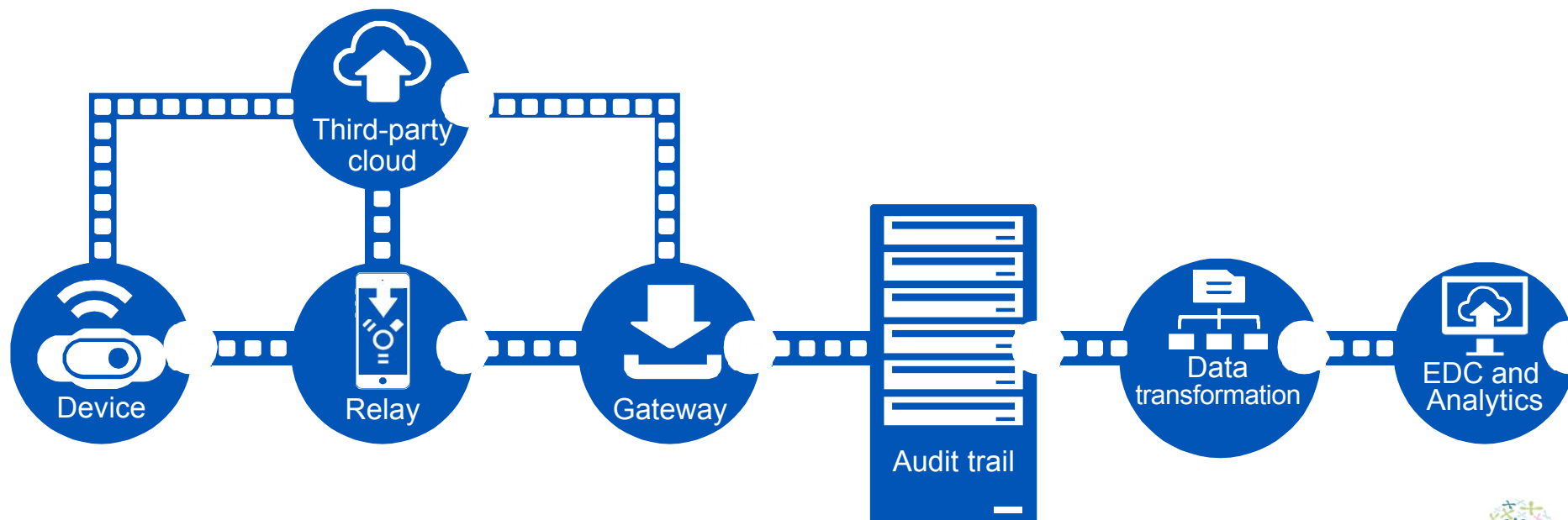
# Nestlé first mobile Health (mHealth) Clinical Trial with Medidata Partner

- Nestlé CDU decided to perform first mHealth Clinical Trial with Medidata Partner
- Mobile process for registration of patient/consumer into database
- Capture and storage of mHealth data in auditable, regulatory compliant manner
- Unified record: Clinical data, Patient/consumer questionnaire data, mHealth summary data

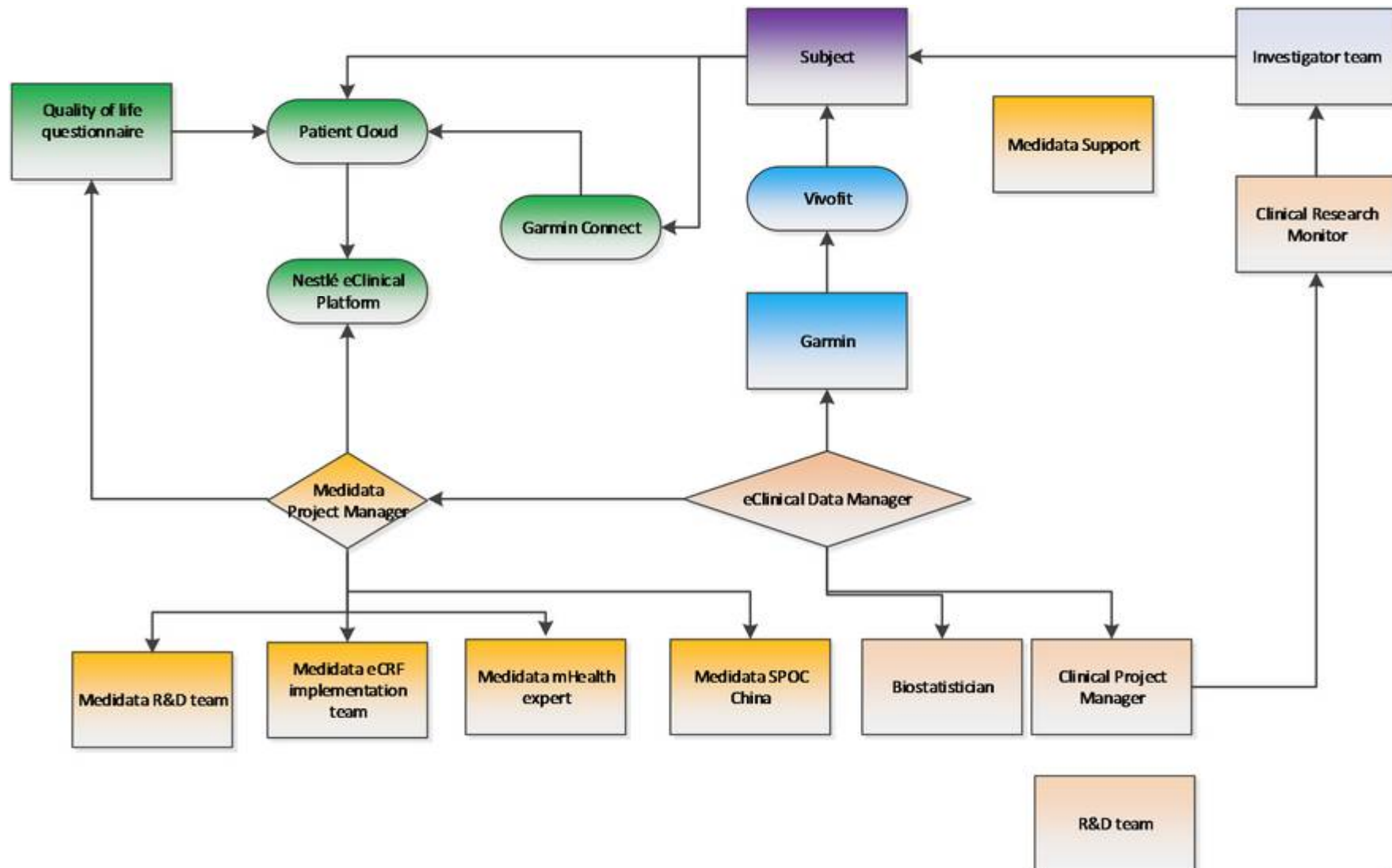


## On courtesy of Medidata: Patient Cloud / mHealth

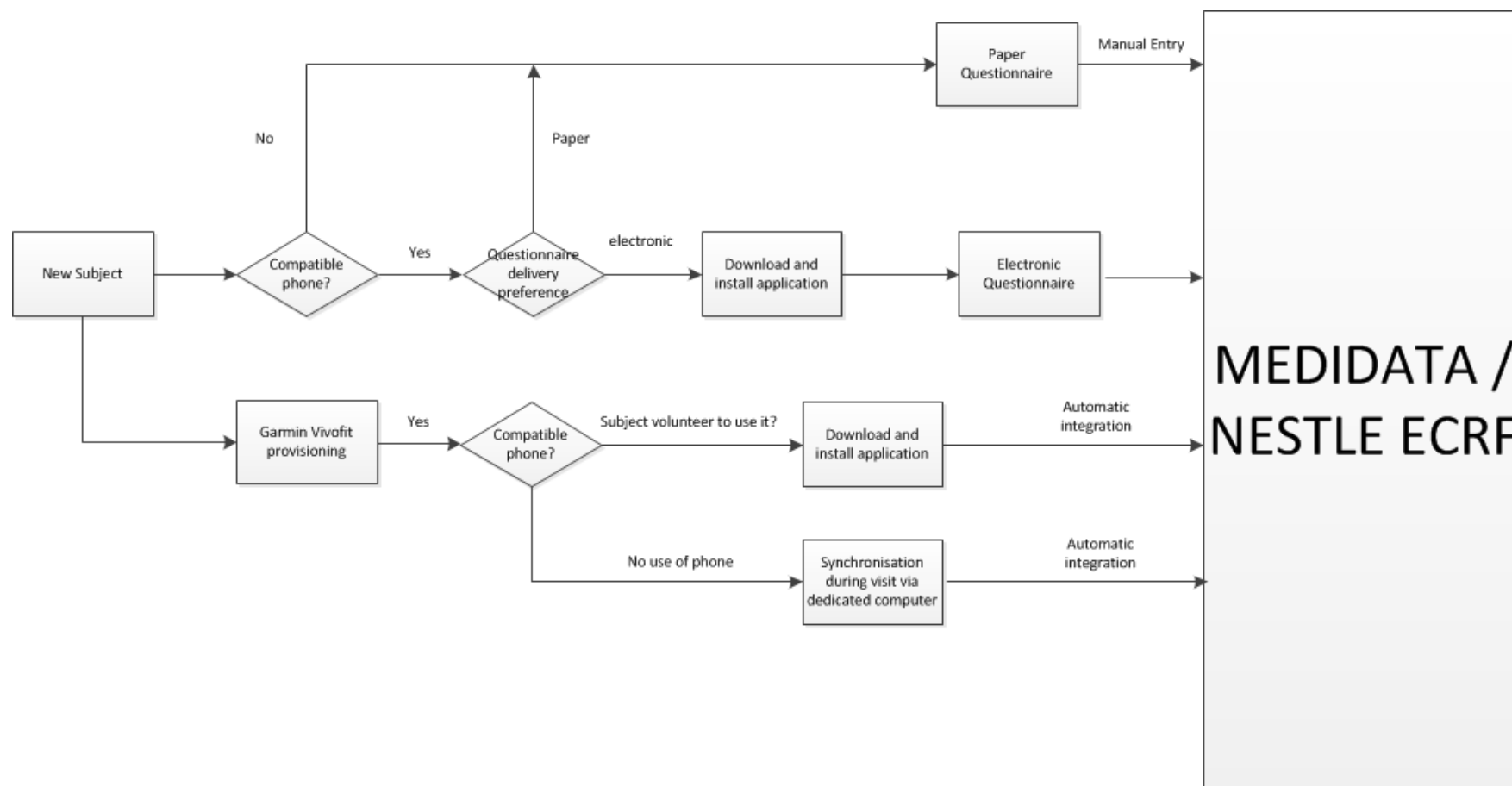
- Mobile patient registration process
- Ingestion and storage of mHealth data in auditable, regulatory compliant manner
  - Device integration
  - Full access to raw data streams
- Insight into potential digital biomarkers from Medidata data science team
- Unified clinical record
  - Clinical eCRF data
  - Patient Cloud ePRO data
  - mHealth summary data
- Operational support for implementing mHealth study, including best practices



# mHealth clinical trial set-up: Interaction Map

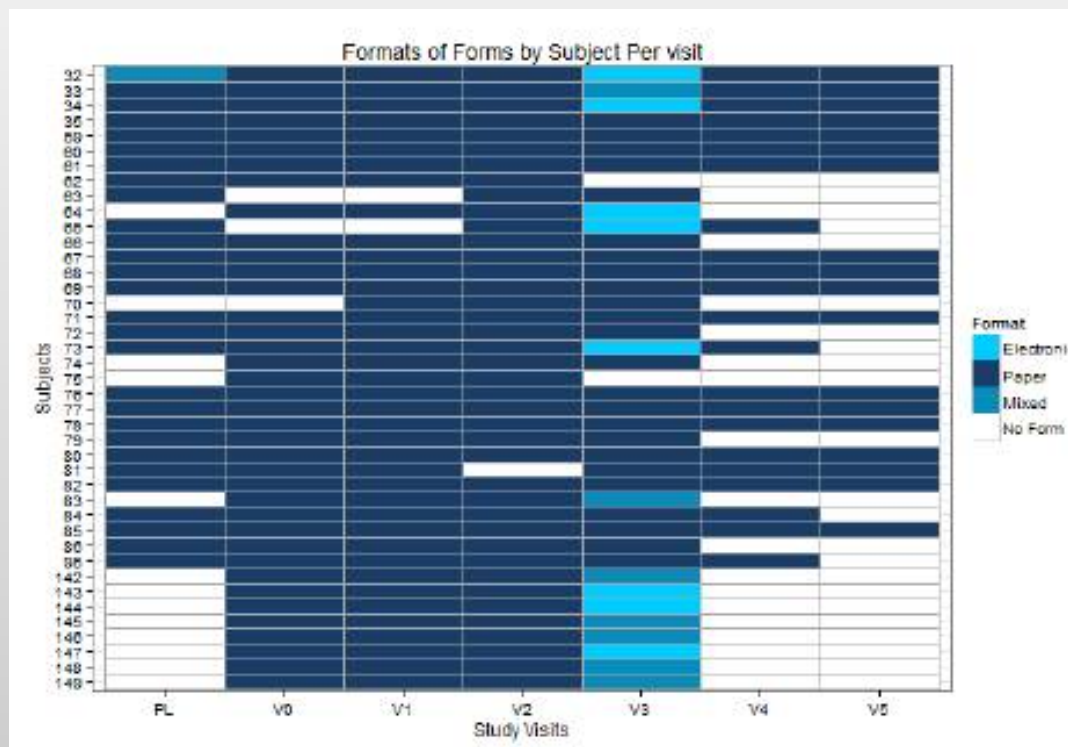


# mHealth clinical trial set-up: Process



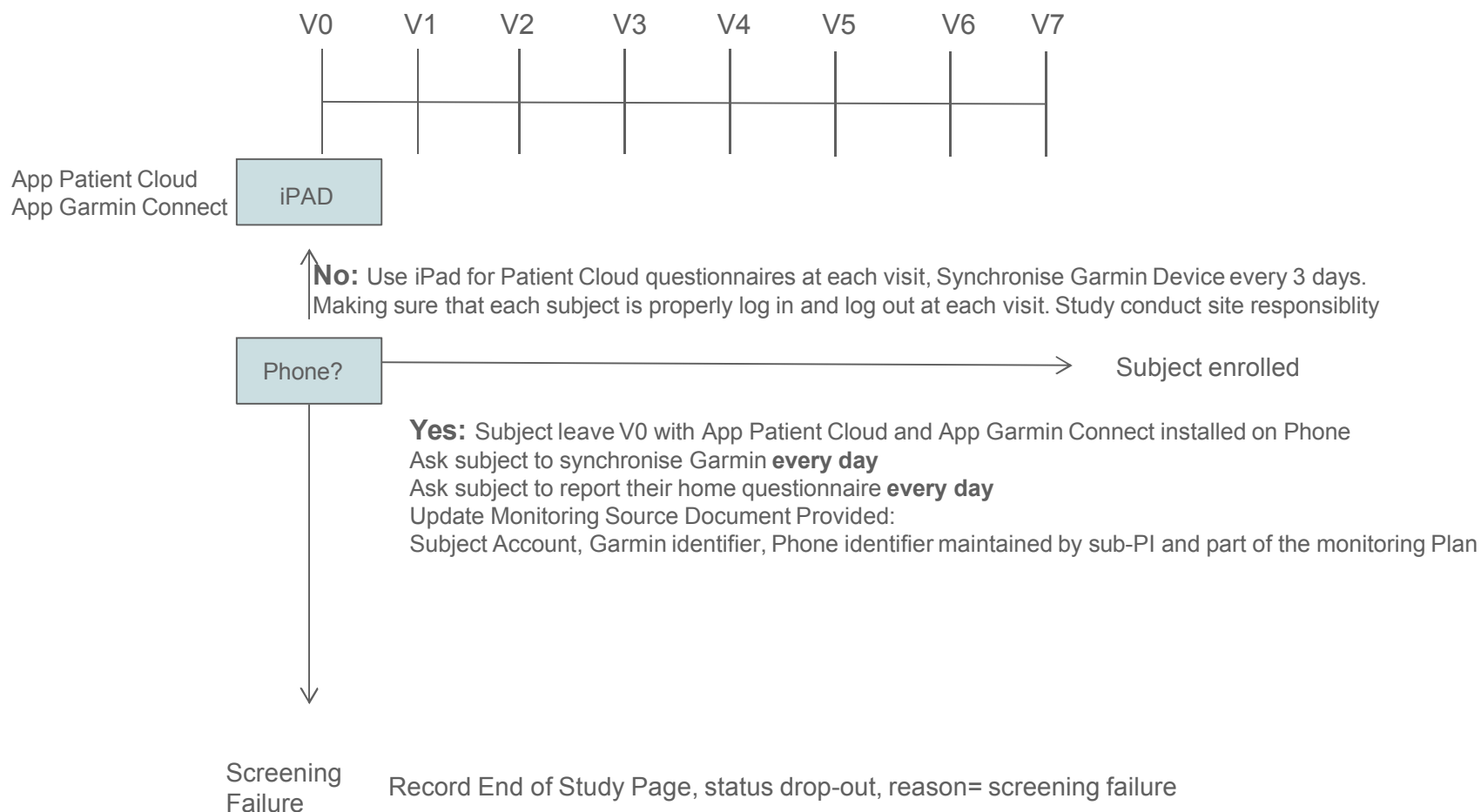


- Ingestion of data and first reports



### Adherence to ePRO

- Pre-requisite: All account activated and Garmin activated
  - CPM send the list to Medidata, Medidata to do on behalf of Nestlé



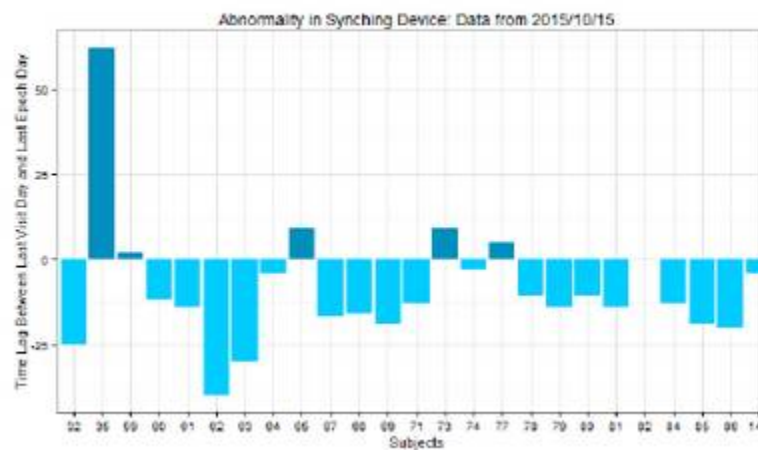
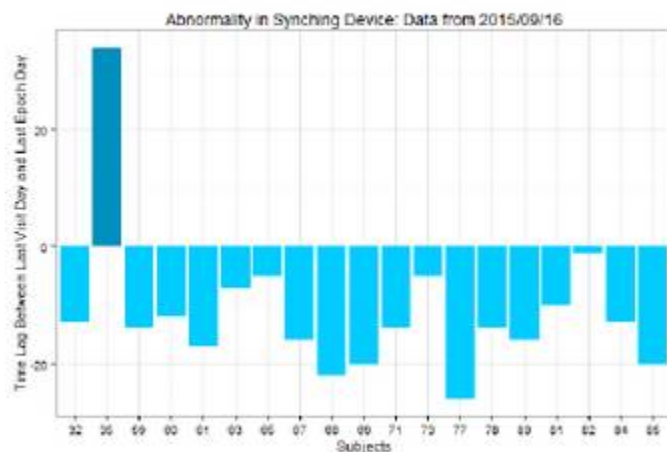
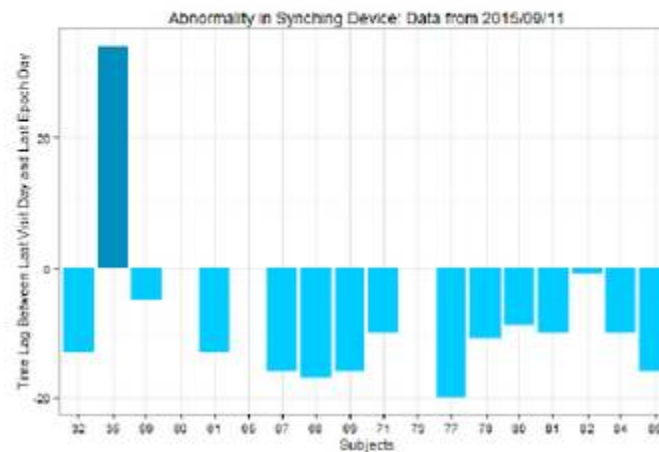
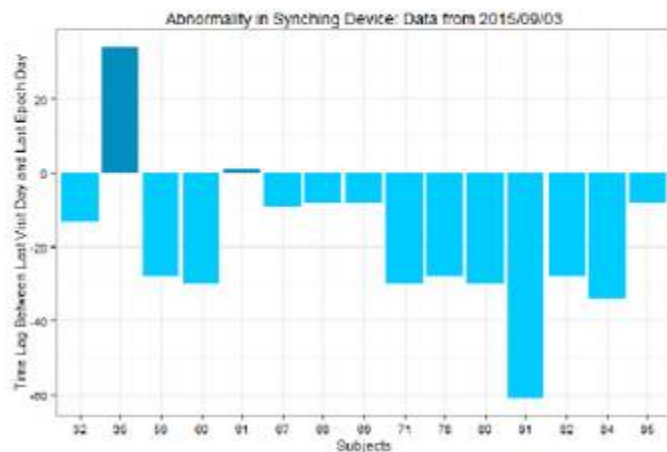
- Roles, Responsibility & Organization:
  - Medidata: pre-register and create Patient Cloud and Garmin account.
  - Medidata & CRA: Support the installation of Patient Cloud and Garmin application on subject phone using Nestlé provided iPad. 2 resources trained available to support the site.
  - Medidata: develop operational visualisation to support overview of operation which can be shared between Nestlé and Site.
  - Nestlé: organise 15 minutes weekly meeting with the clinical team and sub-investigator to review:
    - Visit schedule and support to site requirement 2-3 weeks in advance
    - Synchronisation of Garmin, use of Patient Cloud
    - Monitor source list of Subject / Garmin / Phone
  - Site:
    - Ensure subject is using Patient Cloud and Garmin Connect:
      - Through their phone
      - For subject having no phone through the iPad
    - Review and Synchronise Garmin at each Visit (every 3 days) for subject having missing day of synchronisation



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## Device Compliance

### Did Device synch on last visit?

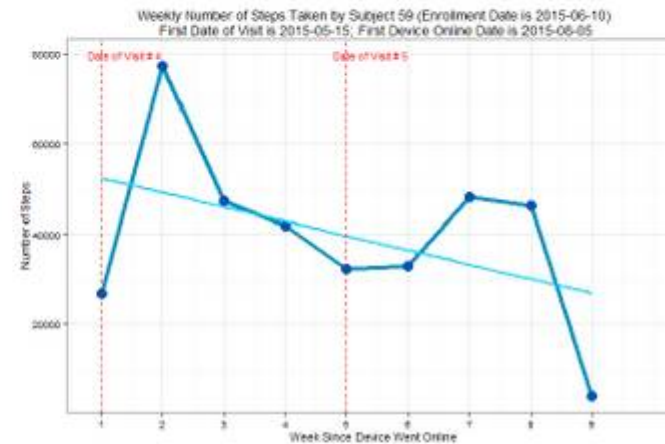


# mHealth Clinical Trial: Operational Visualization

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## Weekly Garmin Device Data

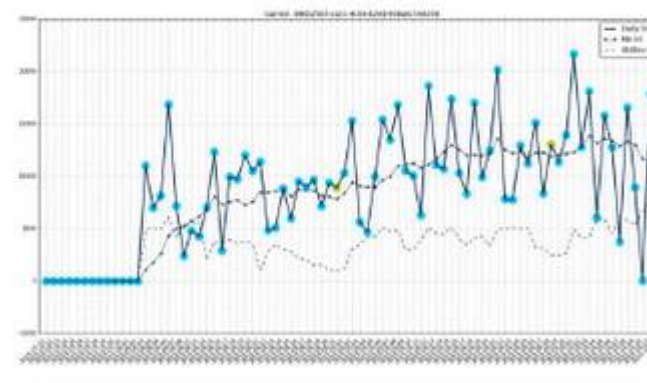
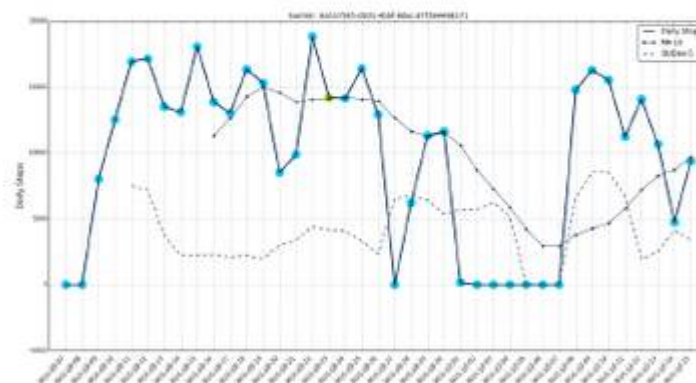
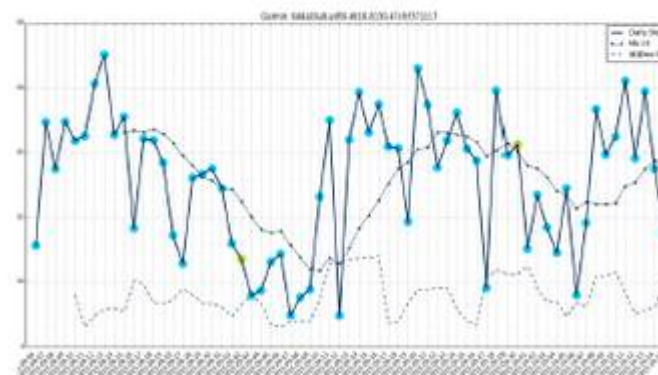
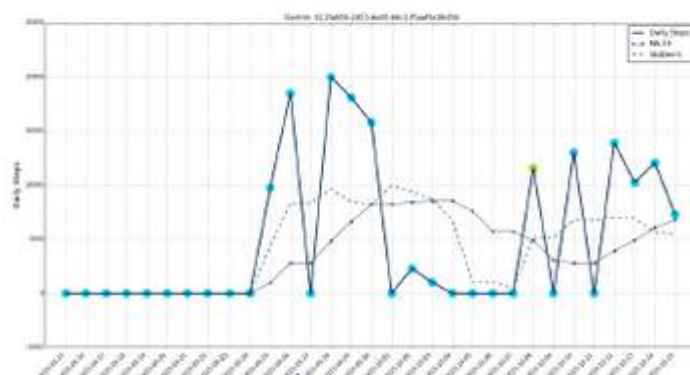
— Weekly number of steps  
— Trend line  
- - - Indicates if week contains a DOV



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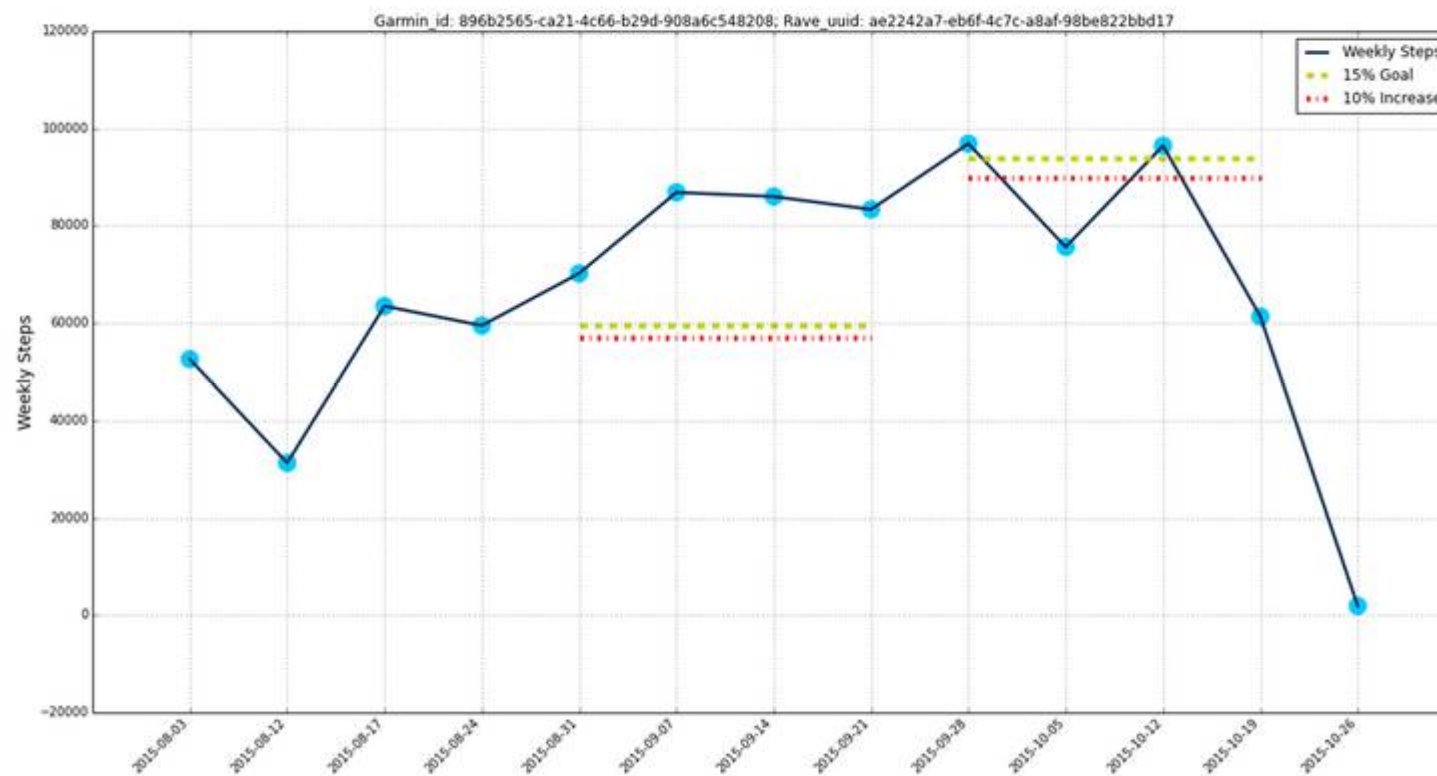
## Daily Garmin Device Data with Annotated Visit Date

— Daily number of steps  
— Rolling Mean 10 days  
- - - Rolling Std Dev 5 days  
● Visit Date





# mHealth Clinical Trial: Operational Visualization



# Lessons learned

	Stakeholder management	Operation	Digital
<b>Success</b>	<ul style="list-style-type: none"> <li>• Sharing of expertise</li> <li>• Clinical Data manager involved at early phase</li> <li>• Team Spirit</li> <li>• Proactive and efficient team</li> </ul>	<ul style="list-style-type: none"> <li>• Recruitment</li> <li>• Timing of project</li> <li>• Site initiation</li> <li>• Operation hurdles tackling</li> </ul>	<ul style="list-style-type: none"> <li>• First eHealth CT in Nestlé</li> <li>• Successful corrective action</li> <li>• Adherence to Garmin</li> <li>• Tracking subject online</li> <li>• Alert on data quality issues</li> </ul>
<b>Challenges</b>	<ul style="list-style-type: none"> <li>• Virtual teams (US, Europe, Asia)</li> <li>• Communication</li> <li>• External partner</li> </ul>	<ul style="list-style-type: none"> <li>• Role &amp; Responsibility</li> <li>• Difference between feelings and facts through the data</li> </ul>	<ul style="list-style-type: none"> <li>• Access to internet in China</li> <li>• Adherence to ePRO</li> <li>• Secure quality of data</li> <li>• Data analysis</li> </ul>
<b>Improvement Area</b>	<ul style="list-style-type: none"> <li>• Definition of Roles &amp; Responsibility</li> </ul>	<ul style="list-style-type: none"> <li>• Report to check data quality at very early stage</li> </ul>	<ul style="list-style-type: none"> <li>• Support to Site and Subject</li> <li>• Investigator must endorse mHealth</li> </ul>



- Using mHealth technologies generates new insight for Clinical Trials
- Implementation requires multidisciplinary teamwork:
  - Telecommunication and technologies platforms & partners.
  - Helpdesk and Services with proper support to ensure adherence to mHealth.
  - Ongoing regulatory assessment and surveillance.
  - New mindset for Clinical Teams with proper protocol.
  - Dedicated teams to create powerful reports for end-users.
- Key consideration for success:
  - Create «mHealth» and «Big data» oriented clinical teams.
  - New techniques and IT platforms need to be implemented for data cleaning.
  - Prepare and drive your Clinical Trial in a «Design Thinking» way.
  - Use partners properly sized for such trials
  - Involve Medical Doctor and Investigator in your mHealth clinical trial strategy.

# Questions?

