PROMETRIKA
A FULL-SERVICE CRO

Innovative Clinical Development Solutions

ePRO Data Integration with Rave®: Case Studies With and Without Patient Cloud®

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Background

PROMETRIKA was the first Medidata CRO partner to become accredited in the Patient Cloud ePRO.

Our first experience with fully integrating an ePRO solution with Rave was using the Patient Cloud.

Since then, we have integrated other ePRO solutions with Rave.

Our most recent experiences demonstrate the stark contrast between integrating a non-Medidata product vs. the Patient Cloud.

Design: Patient Cloud vs. Vendor ePRO
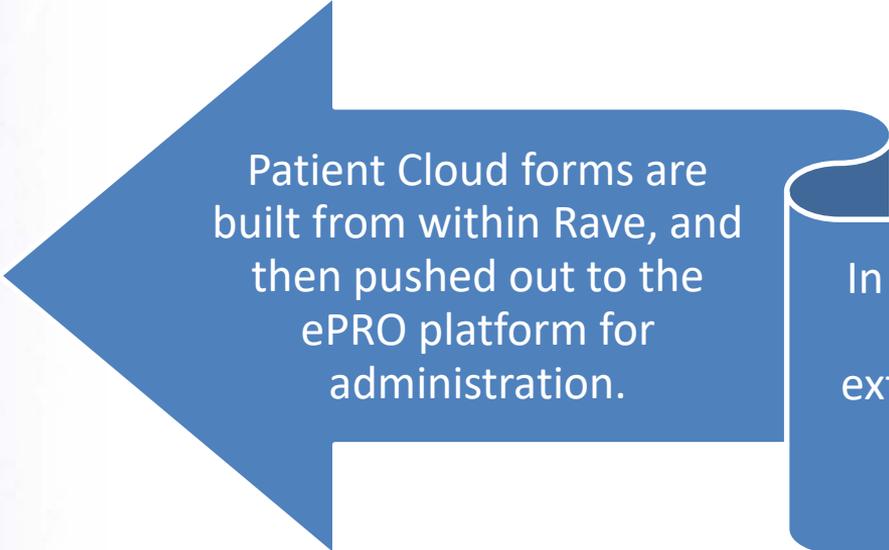
Patient Cloud forms are built from within Rave, and then pushed out to the ePRO platform for administration.
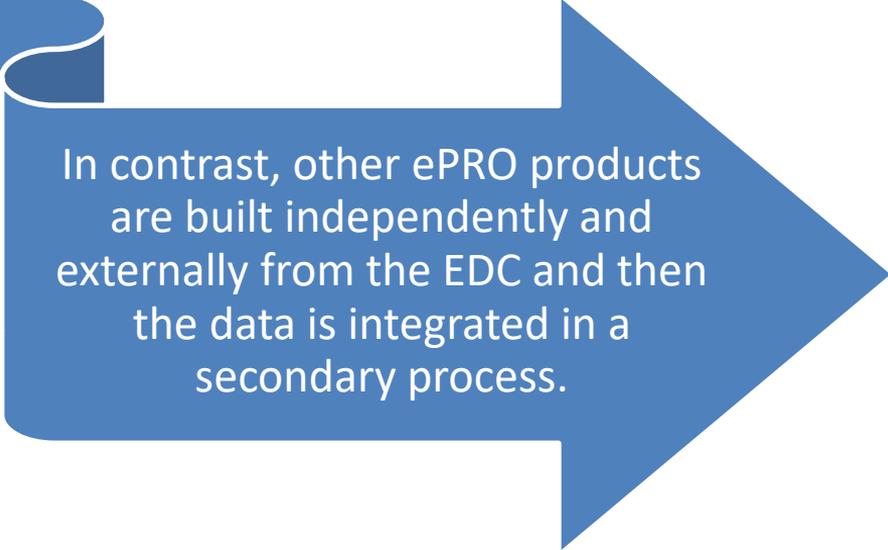
In contrast, other ePRO products are built independently and externally from the EDC and then the data is integrated in a secondary process.

Case Study

- Our most recent experience with integration was with a third-party vendor who is a leader in the ePRO field.

- Their SOPs require that they finalize the ePRO design prior to releasing the specifications to PROMETRIKA for data integration.

- This linear approach created several challenges.

Vendor Data Format Compatibility
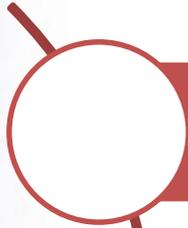
Since the ePRO specs were final, the ePRO eCRFs in Rave had to be designed to support the data format as dictated by the vendor.
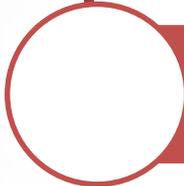
Does not allow DM and biostats to provide input into whether the data format is SDTM compliant or conducive to analysis dataset programming.

This could result in costly extraneous programming to manipulate a poorly formatted data set.

Patient Cloud ePRO Data Format Compatibility
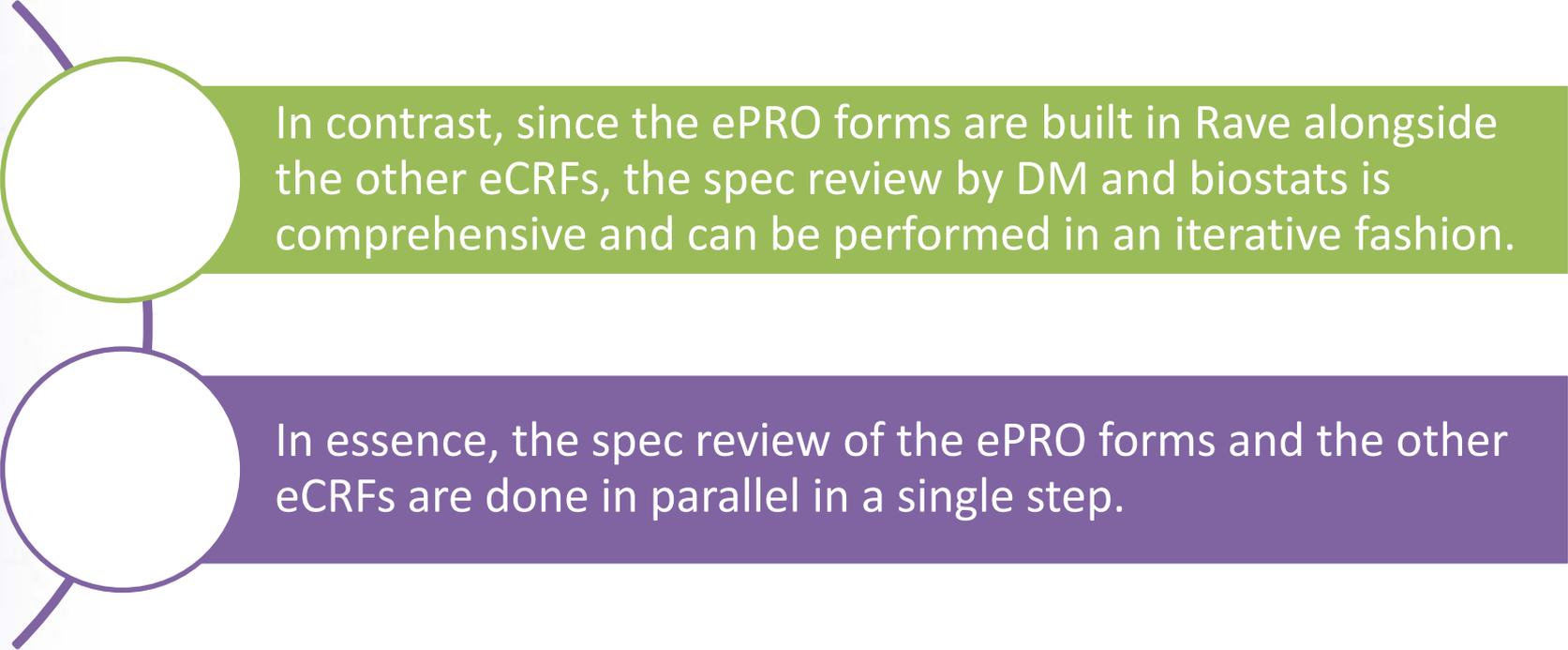
In contrast, since the ePRO forms are built in Rave alongside the other eCRFs, the spec review by DM and biostats is comprehensive and can be performed in an iterative fashion.

In essence, the spec review of the ePRO forms and the other eCRFs are done in parallel in a single step.

Vendor Integration Timeline

The vendor's timeline for go live did not include the integration.

While the data integration did not need to be on the critical path for go live, incompatibilities discovered during the integration process resulted in eCRF changes in Rave.

As these changes and other incompatibilities should be troubleshot prior to EDC go live, best practice should include the integration on the critical path.

Patient Cloud ePRO Integration Timeline

No timeline issues related to integration with the Patient Cloud as the ePRO screens simply go live when Rave is pushed to production.

Conformant with best practice.

Vendor Integration Mapping

As with most integrations, variables need to be mapped across systems.

The study had ~15 PROs, resulting in hundreds of variables to be mapped.

The QC endeavor alone was costly in terms of both resource and time, taking 1 week and 2 FTEs to complete.

Patient Cloud ePRO Integration Mapping

No need to map variables with Patient Cloud, as forms are build in Rave.

Eliminates extra QC step.

Vendor ePRO Completion Workflow

The design specs were shared, but the xml integration specs for RWS were not.

After production, it was discovered that the ePRO system could create new subjects in Rave.

- The integrated IWRS was also set up to create new subjects in Rave.

Edit checks preventing patients from completing ePRO prior to randomization with IWRS were not programmed.

- This resulted in data issues, which needed to be manually resolved.

Patient Cloud ePRO Completion Workflow

Form completion workflow is dictated by a series of custom functions in Rave.

PROMETRIKA can rely on internal programming resources to create complex CFs for fine tuning permissions and ePRO display.

Prevent new subject creation.

Create window for each PRO.

Display PROs as per the schedule of assessments.

ePRO Wish List

- ✓ Agile software development.
  - ✓ Review of specs should be iterative and flexible instead of purely linear.
- ✓ Vendor should have extensive experience with EDC integration.
  - ✓ Default configuration should assume integration, instead of requiring customization.
  - ✓ Integration should be part of go live timeline.
- ✓ xml spec for integration should be available for review

ePRO Wish List

- ✓ Vendor should have custom programming expertise to adapt the system for every sponsor's needs.
- ✓ System should be flexible enough to accommodate programmatic visit/time windows for PROs.
- ✓ Device services
- ✓ Instrument services
  - ✓ Translations
  - ✓ Migrations from paper instrument

PROMETRIKA "NEXT": Technology Roadmap Development

Technology Advisory Committee

- Key stakeholders from all functional areas
- Dedicated forum for developing tech initiatives, including mHealth

Evaluate technology platforms

- Short term implementation
- Long term planning

Digital Strategy

- Rare disease focus
- Specialized, patient-centric approach to data collection for each client
- Medidata Gold Services Partner

Questions