

1. Project title: **Genomic Report and Data Interoperability with Epic**
2. Submitter's name, title, and contact information

Michael Marchant, Director – Health Information Exchange – .  
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3. Names of project leader(s) and team members

Willy Bansi, David Vaillancourt, Scott Nathanson, Marvin Asercion, Paul Robbins

4. A simple short statement (even just one sentence) summarizing what the project does

UC Davis Health built a context aware link in Epic giving providers access to discrete data generated from genomic reports provided by Foundation Health with live link access to clinical trial information embedded in the report.

5. A project narrative that:

- Describes the problem being solved and the project goals

Genomic reports are delivered to UC Davis Health by mail, fax or by hand and then are scanned into the EHR and placed in the media tab with other scanned documents. The project goal is to take those scanned documents and create a dynamic frame of discrete data and links in context in the patient's chart with access to information provided by the genomic reporting agency and allow real time access and retrieval of those reports.

- Emphasize the solution and innovation, rather than technical detail

This is an embedded link in Epic, which will render the Genomics data placed in an external data storage. The connection leverages a FHIR API along with Single Sign On (SSO) technology. SSO is used to authentication users between the two systems, and FHIR Resources are used to pass the Patient and Provider information between Epic and Healthshare. The Embedded viewer GUI (Graphical Unit Interface) mimics Epic's and gives the user an experience that they never left Epic.

- Tell how the solution has impacted customers/users

Providers and Genetic Counselors were spending time looking for scanned reports in Epic's media tab and finding reports were difficult due to the number of scanned documents found there. The integration saves them time as they can easily locate patient reports. The embedded integration adds interactivity and search capability. Providers can search for key words and it gives them the ability to quickly narrow down available clinical trials based on study locations, Genes Types or Bio Markers. The report includes links that take providers to the ClinicalTrials.gov site to get more detail on the specifics of the research study.

- Explains how project success was measured

- Budget & Project Schedule: We were on Budget and Project went live on schedule
- Customer Satisfaction: Gathered requirements from our customers to make sure all the deliverables were met
- Reporting: All transactions and activities are being logged and reports are in place showing the user activities.
- Team Satisfaction: As we were developing a new capability and provided team members an opportunity to innovate, all team members were enthusiastic and engaged and their productivity showed the results
- Quality of work: We had stakeholders who were able to perform quality audits to make sure their requirements were met.

- Highlighted collaboration with other locations, departments, or teams

- Multiple Teams were involved in the collaboration – Systems Integration, Epic Applications, Cancer Center Providers, Infrastructure Team, Foundation Medicine and our vendors (J2 and InterSystems).

- Timeframe of deployment
  - This project took roughly 4 months from start to finish.
- Describe the technology utilized
  - This integration uses Web Services, FHIR with OAuth, Single Sign On as well as the Epic Interconnect and InterSystems Healthshare platform.
- Optional: Relevant screenshots

The **Genomics Results** activity opens the **Genomics** tab. Available result reports are listed. Double-click the report link to open the desired report.

Date	Description	Status	Provider
11/13/2019	FoundationOne CDX	Report Received	Ruskin, Rachel
11/12/2019	FoundationOne Heme	Report Received	Canter, Robert

At the top of the report, the header provides information about the test.

- Click the PDF hyperlink to view the Complete Report. The PDF report was previously viewed when scanned to the Chart Review Media tab.
- Click through the tabs to access the sections of the report for **Genomic Results**, **Therapies**, **Clinical Trials**, and **Variants of Unknown Significance**.

View Genomic Results:

*Genomic Results Tab*

## View Therapies:

Genomic Results (9) **Therapies (15)** Clinical Trials (26) Variants of Unknown Significance (8)  Only for this tumor type

*Note: Genomic alterations detected may be associated with activity of certain FDA-approved drugs; however, the agents listed in this report may have little or no evidence in the patient's tumor type. Neither the therapeutic agents nor the trials identified are ranked in order of potential or predicted efficacy for this patient, nor are they ranked in order of level of evidence for this patient's tumor type.*

**Trastuzumab-pkrb** (ERBB2)  
FDA Approved for other tumor types

**Lapatinib** (ERBB2)  
FDA Approved for other tumor types

**Trastuzumab** (ERBB2)  
FDA Approved for other tumor types

**Trastuzumab-qyyp** (ERBB2)  
FDA Approved for other tumor types

**Ado-trastuzumab emtansine** (ERBB2)  
FDA Approved for other tumor types

**Trastuzumab-anns** (ERBB2)  
FDA Approved for other tumor types

**Pertuzumab** (ERBB2)  
FDA Approved for other tumor types

**Afatinib** (ERBB2)  
FDA Approved for other tumor types

**Approved Indications:** Trastuzumab-pkrb is FDA approved as a biosimilar therapy to trastuzumab. Trastuzumab-pkrb is a monoclonal antibody that targets the protein ERBB2/HER2 and is FDA approved in combination with chemotherapy for HER2-positive (HER2+) early and metastatic breast cancer and as a monotherapy for HER2+ metastatic breast cancer previously treated with chemotherapy.

**Gene Association:** On the basis of clinical studies in multiple tumor types, ERBB2 amplification, overexpression, or activating mutations may confer sensitivity to anti-HER2 therapies such as trastuzumab-pkrb <sup>194 195 199 210 271 272 273 274 275 297</sup>. In patients with HER2+ early stage breast cancer, trastuzumab-pkrb combined with chemotherapy elicited a pathological CR rate of 46.8% <sup>297</sup>.

**Supporting Data:** A Phase 3 trial demonstrated comparable pathological CR rates (46.8% vs. 50.4%) for patients with treatment-naïve, early stage operable HER2-positive breast cancer treated with either trastuzumab-pkrb or trastuzumab in combination with chemotherapy <sup>297</sup>. In patients with HER2+ breast cancer and in healthy adults, trastuzumab-pkrb demonstrated comparable pharmacokinetic, safety, and immunomodulation profiles to trastuzumab (Stebbing et al., 2017; 28592386; Esteva et al., 2018; 29330636).

## Therapies Tab

## View Clinical Trials:

- Filter clinical trial results by location, Genes, or keyword(s)
- Click an NCTID hyperlink to go directly to the NLM listing on ClinicalTrials.gov

Genomic Results (9) Therapies (15) **Clinical Trials (26)**

Variants of Unknown Significance (8)

*IMPORTANT: Clinical trials are ordered by gene and prioritized by: age range inclusion criteria for pediatric patients, proximity to ordering medical facility, later trial phase, and verification of trial information within the last two months. While every effort is made to ensure the accuracy of the information contained below, the information available in the public domain is continually updated and should be investigated by the physician or research staff. This is not meant to be a complete list of available trials. In order to conduct a more thorough search, please go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and use the search terms provided below. For more information about a specific clinical trial, type the NCT ID of the trial indicated below into the search bar.*

Gene	Title	Phase	Targets	Locations	NCTID
ARID1A (S617fs*6)	ATR Kinase Inhibitor VX-970 and Irinotecan Hydrochloride in Treating Patients With Solid Tumors That Are Metastatic or Cannot Be Removed by Surgery	PHASE 1	ATR	California, Connecticut, Florida, Massachusetts, Michigan, Missouri, North Carolina, Pennsylvania, Tennessee	NCT02595931
ARID1A (S617fs*6)	Ascending Doses of AZD6738 in Combination With Chemotherapy and/or Novel Anti Cancer Agents	PHASE 1/2	ATR, PARP, PD-L1	California, New York, Saint Herblain (France), Villejuif (France), Seongnam-si (Korea, Republic of), Seoul (Korea, Republic of), Cambridge (United Kingdom), London (United Kingdom), Manchester (United Kingdom), Sutton (United Kingdom)	NCT02264678
ARID1A (S617fs*6)	Trial of Topotecan With VX-970, an ATR Kinase Inhibitor, in Small Cell Cancers	PHASE 1/2	ATR	Maryland	NCT02487095
ARID1A (S617fs*6)	Veliparib (ABT-888), an Oral PARP Inhibitor, and VX-970, an ATR Inhibitor, in Combination With Cisplatin in People With Refractory Solid Tumors	PHASE 1	PARP, ATR	Maryland, Massachusetts, Texas	NCT02723864

## Clinical Trials Tab

Report Date **Nov 13, 2019** Tumor Type **Uterus endometrial adenocarcinoma (NOS)** Specimen Site **Lymph Node**

Case # **ORD-0685** Specimen Type **Slide Deck**

Test Type **Foundation** Specimen Received **Oct 29, 2019**

Complete Report **PDF** Date of Collection **Sep 17, 2019**

Genomic Results (9) Therapies (15) Clinical Trials (26) Variants of Unknown Significance (8)

**NLM Listing for NCT02595931**

Help guide our efforts to modernize [ClinicalTrials.gov](#). Send us your [comments](#) by March 14, 2020.

NIH U.S. National Library of Medicine  
**ClinicalTrials.gov**

Home > Search Results > Study Record Detail  Save this study

Trial record 1 of 1 for: **NCT02595931**

Previous Study | [Return to List](#) | Next Study

**VX-970 and Irinotecan Hydrochloride in Treating Patients With Solid Tumors That Are Metastatic or Cannot Be Removed by Surgery**

The safety and scientific validity of this

Gene Title

ARID1A (S617fs*6)	ATR Kinase Irinotecan Patients W Metastatic Surgery
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Connecticut, Massachusetts, Missouri, NCTID NCT02595931

View Variants of Unknown Significance:

Report Date **Nov 13, 2019** Tumor Type **Uterus endometrial adenocarcinoma (NOS)** Specimen Site **Lymph Node**

Case # **ORD-0685340-01-SIT** Ordering Facility **UC Davis Comprehensive Cancer Center** Specimen Type **Slide Deck**

Test Type **FoundationOne CDX** Ordering Physician **Ruskin, Rachel** Specimen Received **Oct 29, 2019**

Complete Report **PDF** Pathologist **Affy, Alaa** Date of Collection **Sep 17, 2019**

Genomic Results (9) Therapies (15) Clinical Trials (26) **Variants of Unknown Significance (8)** filter... Reset

Note: One or more variants of unknown significance (VUS) were detected in this patient's tumor. These variants may not have been adequately characterized in the scientific literature at the time this report was issued, and/or the genomic context of these alterations makes their significance unclear. We choose to include them here in the event that they become clinically meaningful in the future.

Gene	Variant
RBM10	V238M
NTRK2	M713K
ARFRP1	A123V
ASXL1	K85R
PTEN	M35K
CCND1	E279*

Microsatellite status  
MSS

Tumor Mutation Burden  
intermediate; 6.3 mutations-per-megabase

Variants of Unknown Significance Tab