Blazing the Precision Medicine Trail: Data Inter-operability and Sharing Across the Ecosystem
Session #3, March 5, 2018
Thomas D Brown, MD, MBA
Executive Director, Swedish Cancer Institute (SCI)
Disclosures

Consulting
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Speaker’s Bureau
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Speaker Introduction

Thomas D Brown, MD, MBA
Executive Director, Swedish Cancer Institute (SCI)
Co-Chair PSJH Personalized Medicine Program
Co-Chair PSJH Cancer Leadership Council
Seattle, Washington
Learning Objectives

• Learn the components of an integrated clinical Precision Medicine program
• Learn the clinical and research needs relating to data interoperability and sharing
• Identify the challenges of data sharing across clinical networks
• Identify future trends in Precision Medicine, and the implications for data systems and management
Providence St. Joseph Health Overview

- **Providence Health & Services**
  - Alaska
  - Western Washington, including Swedish Health Services and Pacific Medical Centers

- **Providence Health & Services**
  - Oregon
  - Providence Health Plan

- **Providence Health & Services**
  - Western Washington
  - Kadlec Regional Medical Center

- **Providence Health & Services**
  - Eastern Washington
  - Northern California (Plumas, Napa, Sonoma counties), including St. Joseph Heritage Healthcare

- **Providence Health & Services**
  - Southern California (Los Angeles County), including captivating Medical Foundation

- **St. Joseph Health**
  - Southern California (Orange and San Bernardino counties, the High Desert), including Hoag Health and St. Joseph Heritage Healthcare

- **St. Joseph Health**
  - West Texas
  - Eastern New Mexico, including Covenant Health, Covenant Medical Group and FirstCare Health Plans

**Key Statistics**

- 50 Hospitals
- 829 Clinics
- 90 Non-Acute Services
- 14 Supportive Housing Programs
- 111k Caregivers
- 38k Nurses
- 20k Physicians
- 2 Health Plans
- 1.9m Covered Lives
- $1.6b Community Benefit
SCI Mission Statement

To provide cancer patients the best chance of *survival* and the highest *quality* of life while striving to *prevent* and *eliminate* cancer through *research* and *innovation*.

SCI Vision Statement

To be a national and international *leader* in providing *innovative* cancer care of the highest *quality*, that is *patient* and *family centered*, and determined by both *clinical* and *biological* characteristics of each individual.

SCI Values

Collaboration | Compassion | Excellence | Innovation | Mentorship | Respect | Responsibility | Safety | Transparency
In 1932, Swedish Purchases Million-Volt X-Ray Machine making SCI the first radiation medicine facility west of Mississippi river.
Swedish Cancer Institute Overview

• Nine multi-disciplinary disease sites
  o Over 200 members of SCI with 88 providers employed
• Comprehensive Supportive Care Services
  o 18 programs
• Approximately 8,000 new cancer patients / year
  o 6082 analytic cases in 2016
• On average, 500 patients accrued into clinical trials annually (including PMRP protocol)
Clinical practice at the SCI is predicated on a research driven, evidence-based, multi-disciplinary, multi-professional, disease site oriented, patient-centered care model, in the context of Personalized Medicine. Personalized Medicine in this context focuses on two meanings:

1. Caring for the whole patient, to include addressing patient and family socioeconomic, psychological, environmental, and other supportive care needs;

2. Utilizing molecular (gene, protein, epi-genetic) information from the patient or their tumor to address cancer risk, prevention, screening, early and accurate diagnosis, treatment of disease, and survivorship.
Multi-Faceted Approach

Disease Site Orientation
- Breast
- Gastrointestinal (GI)
- Genitourinary (GU)
- Gyn/Onc
- Head and Neck
- Hematologic Malignancies
- Neuro/CNS
- Sarcoma/Melanoma
- Thoracic
SCI Personalized Medicine Program

2014 Mar
PMP Panel 1st Edition
(68 gene panel)

2014 Sep
Personalized Medicine Research Program (PMRP) Protocol (IRB approved)

2015 Jan
Molecular Tumor Board Launch

2015 Nov
PMP IT Platform (Syapse) Launch

2015 Sep
Personalized Medicine Research Program (PMRP) Protocol (IRB approved)

2015 Nov
PMP IT Platform (Syapse) Launch

2016 Mar
Innovative Therapeutics Unit (Early Phase Clinical Trials Unit) Open
SCI PMRP: Eligibility Criteria

Inclusion Criteria

• Patients with active malignancies or selected pre-malignant conditions to include: myelodysplastic syndromes (MDS), actinic keratosis, Barrett’s esophagus, cervical dysplasia, colonic polyps, lung metaplasia, and oral leukoplakia

• 18 years of age, or older

• ECOG performance status of 0 to 2

• A candidate for anti-cancer therapy

• Life expectancy of at least three months

• Measurable or evaluable disease is not required; e.g. patients in the adjuvant setting may be enrolled, if clinically appropriate
SCI PMRP: Eligibility Criteria (cont’d)

• Prior malignancy or multiple current malignancies allowed
• Patients who previously had gene sequencing are allowed
• All patients must be informed of the investigational nature of this study, and must give written informed consent, in accordance with institutional and federal guidelines

Exclusion Criteria
• Patients who are not able to understand and consent for themselves to the PMRP
• Patients who do not have sufficient tissue available for the PMP Panel
SCI PMRP: Recruitment/Enrollment

• **Enrollment:** 1,034 pts (as of January 22, 2018); initial focus on solid tumors

• **Insurance Status:** No restrictions

• **Cost to Participate in PMRP:** None (PMP Panel ordered by provider, and billed based on “medical necessity”)

• **Language:** Consent form in English, Vietnamese, Korean, Japanese, Chinese (Mandarin & Cantonese), Russian and Spanish
SCI PMRP: Workflow

**Testing**
- Patient receives gene sequencing test (based on medical necessity)

**Enrollment**
- Patient signs consent

**Follow-up**
- Patient is followed, at least annually, to review disease status and to identify need for clinical interpretation update

**Update**
- Provider and patient receive updated reports
SCI/PSJH PMP: Informatics Platform

- Machine Learning
- Genomic Data & Tools (e.g. TCGA)
- Data Sharing (e.g. OPeN; Genie)
- Molecular Pathology (e.g. NGS)
- External Labs (e.g. genetic & genomic testing)
- Clinical Interpretation (e.g. annotation, therapeutic options, literatures)
- State/National Registries
- Disease Site Registries (Research)
- The Social Security Death Index (SSDI)
- ClinicalTrial.gov
- PSJH Enterprise Data Warehouse
  - Clinical & Financials
  - Cancer Registries
- Clinical & Genomics
- Clinical Trials Management System & Biorepository
- Synoptic Pathology
- Clinical Trials (Research)
- Electronic Medical Records
- Collect, manage, integrate, visualize, analyze & share

Platforms
- Existing Interface
- 2018 -
- TBD
SCI PMP PANEL: ALTERATIONS BY CATEGORY

PMRP Enrollment: 850 patients
SCI/PSJH Syapse: Clinical History

- **Encounter Summary**
  - Outpatient Encounters: 3
  - Inpatient Encounters: 2
  - Emergency Room: 2

- **Medication Orders**
  - DOXORUB...: 2
  - TAMOXIF...: 2
  - CAPECIT...: 2
SCI/PSJH: Syapse: Lab Results
SCI/PSJH Syapse: PMP Panel Results

Individual Reports

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<th>0 actionable variants Found</th>
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1 Therapies in patient's tumor type
- Regorafenib

2 applicable variants Found
- FBXW7 [FBXW7 R465C]
- BRAF [BRAF G469E]

4 Therapies in another tumor type
- everolimus
- temsirolimus
- Temelatinib
- sorafenib

Therapies in Patient's Tumor Type

BRAF
- Therapy: Regorafenib
- Effect: Increased sensitivity
- FDA Approved? Yes
- FDA Approved for Patient's Indication? Yes

Therapies in Tumor Types Other than Patient's

FBXW7
- Therapy: everolimus
- Effect: Increased sensitivity
### SCI/PSJH Syapse: PMP Panel Results (cont'd)

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<th>BRAF</th>
<th>FDA Approved for Patient's Indication? No</th>
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<td>Therapy</td>
<td>Trametinib</td>
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<tr>
<td>FDA Approved? Yes</td>
<td>FDA Approved for Patient's Indication? No</td>
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**Potential Clinical Trials**

- **FBXW7**
  - Dose Escalation Study of MLN0128 in Subjects With Advanced Malignancies
  - Phase I Dose Escalation Study of VS-5584 in Subjects With Non-Hematologic Malignancies or Lymphoma

- **FBXW7**
  - A Phase 1 Study of MM-141 in Patients With Advanced Solid Tumors
  - Clinical Study Of RSK/mTOR Inhibitors In Combination With An Oral MEK Inhibitor Or Irinotecan In Patients With Advanced Cancer

- **FBXW7**
  - Phase 1b Study of MLN0129 in Combination With MLN1171 in Adult Patients With Advanced Nonhematologic Malignancies
  - A Study OF PF-06212384 Plus FOLFIRI Versus Bevacizumab Plus FOLFIRI In Metastatic Colorectal Cancer

- **FBXW7**
  - Phase 1 Dose Escalation Study of ARQ 092 in Adult Subjects With Advanced Solid Tumors and Recurrent Malignant Lymphoma
  - Tivantinib and Temsirolimus in Treating Patients With Solid Tumors That is Metastatic or Cannot Be Removed By Surgery

- **BRAF**
  - A Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, and Anti-Cancer Activity of Trametinib in Combination With Paclitaxel in Subjects With Solid Tumors
  - A Phase 1b Study of MDL3240A (an Engineered Anti-PD-L1 Antibody) in Combination With Cabozantinib in Patients With Locally Advanced or Metastatic Solid Tumors

- **BRAF**
  - Regorafenib+FOLFIRI Versus Placebo+FOLFIRI as 2nd Line Tx in Metastatic Colorectal Cancer
  - Pharmacokinetics and Safety of Regorafenib (BAY73-4506) In Cancer Subjects With Severe Renal Impairment
SCI/PSJH Syapse: Similar Patients

Show all patients with Lung

77 patients in population. (Out of 706 patients) Clear query

Breakdown by Subtype

- Squamous cell carcinoma: 15 patients (19%)

Breakdown by Altered Gene

- KDR: 30%
- TET2: 32%
- TPS3: 22%
- KRAS: 27%
- CDKN2A: 13%
- RET: 15%
- EGFR: 15%
- TYMS: 10%
- ENMT3A: 8%
- PIK3CA: 8%

Source: Customer Patient Data
SCI MOLECULAR TUMOR BOARD

- **Co-chairs**: Anna Berry, John Pagel, Charles Drescher
- **Purpose**: multidisciplinary case review focused on clinically relevant gene alterations and associated molecular pathways, with aim of facilitating patient management decisions.
- **Conference Structure**:
  - Average 3-4 cases including follow-up cases
  - Cases submitted by physicians and selected by Dr. Berry
  - Special Sessions (e.g. Implications for Germline Genetic Testing)
HISTORY: Papillary serous adenocarcinoma of the ovary first presented in 2011, had debulking surgery and adjuvant Taxol and Carboplatin. Recurred in January 2013, abdominal wall, received Letrozole but progressed quickly with a pelvic mass and attempted resection, would have required permanent colostomy. Postoperative radiation therapy in October 2013. Then developed extensive abdominal disease. She was seen at MD Anderson and sequenced by Foundation Medicine. NF2 and CDKN2A/B mutations were found. Mekinist (only 4/wk due to rash) April 2014 to March 2015 with some response, then progression. Avastin, Taxol, Carboplatin June to Nov 2015, then Gemzar to Jan 2016, then Regorafinib (reduced dose due to side effects) until June 2016, then Afinitor to August 2016, then Keytruda. Bowel obstruction in Nov 2016. MATCH lab could not confirm results (NF2 or CDKN2). Back to Regorafinib in Feb 2017.
Recurrent low grade papillary serous carcinoma of ovary (2013 sample, sigmoid nodule).
**SCI MOLECULAR TUMOR BOARD CASE – Mar, 2017**

*Sharpless and Sherr, Nature Reviews Cancer, 2015*
POSSIBLE THERAPIES:
- Afinitor / Everolimus - mTOR kinase inhibitor, immunosuppressant.
- Torisel / Temsirolimus - mTOR inhibitor.
- Mekinist/Trametinib – MEK inhibitor.
- Tykerb/Lapatinib – EGFR/HER2 inhibitor.
- Defactinib – FAK inhibitor.
- Ibrance/Palbociclib – CDK4/6 inhibitor (TAPUR match).

POSSIBLE CLINICAL TRIALS:
- NCT02943317: Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of Defactinib in Combination With Avelumab in Epithelial Ovarian Cancer (Verastem, TN and others not open yet)
- NCT02546531: Defactinib Combined With Pembrolizumab and Gemcitabine in Patients With Advanced Cancer (Wash U)
- NCT02352844: Everolimus in Patients With Advanced Solid Malignancies With TSC1, TSC2, NF1, NF2, or STK11 Mutations (Wash U)
- NCT02897375: Palbociclib With Cisplatin or Carboplatin in Advanced Solid Tumors (Pfizer, Emory)
PSJH Personalized Medicine Program (PMP) 
Program Vision and Goal

- **Vision**: Create an enterprise wide genomics and personalized medicine program to best serve our patients and support our institutes

- **Goal**: Leverage the knowledge of existing programs within PSJH to create a nationally recognized clinical and research genomics program
# PSJH PMP Focus Groups

**Co-Chairs: Thomas Brown, MD, MBA & Walter Urba, MD, PhD**

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<th>FOCUS GROUPS</th>
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<th>PURPOSE/PRIORITIES</th>
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| Bioinformatics               | Carlo Bifulco, MD                  | Genomics data storage/cloud-based bioinformatics analysis pipeline and clinical data integration  
                              | Paul Tittel                        |                                                                                  |
|                              | Ora Gordon MD, MS                  |                                                                                  |
| Registry/Repository          | Charles Drescher, MD               | System wide registry/consent template with networked bio-                        |
|                              | Ora Gordon MD, MS                  | repositories                                                                     |
| Laboratory Specifications    | Carlo Bifulco, MD                  | Alignment and determination of genomics services, platforms, policies             |
|                              | Anna Berry, MD                     | and standards                                                                    |
|                              |                                    |                                                                                  |
| Clinical Applications        | Philip Gold, MD                    | Molecular tumor board, patient engagement center integration into PH&S genomics   |
|                              | Karen Appelbaum                    | initiative, and education components                                            |
| Research                     | John Pagel, MD, PhD                 | Registry protocol and resource inventory, governance of data usage                |
|                              | Rom Leidner, MD                    |                                                                                  |
| Business & Logistics         | Nancy Frisco                       | Development of business plan/pro-forma and budget                                 |
|                              | Jim Yates                          |                                                                                  |
Key Components – PSJH PMP

• Patient Engagement Center
• 300~ Gene Alteration Panel
• IRB Approved Registry Trial
• Implementation of Bioinformatics Platforms (e.g. Syapse)
• Regional Molecular Tumor Boards
• Bio-repository Platform
• De-identified data sharing (OPeN & AACR Project GENIE)
PSJH PERSONALIZED MEDICINE PROGRAM (PMP) PROGRAM VISION AND GOAL

Phase I – PSJH Personalized Medicine Program (PMP) at Large Regional Cancer Centers

Phase II – PSJH PMP expansion across the enterprise

Phase III – Whole Exome and Transcriptome Sequencing, Proteomics, Micro-biomics, and Immune profiling
An Evaluation of Wellness in Breast Cancer Survivors

Ellis, E; Price N; Rinn K; Kaplan, H; Tameishi, M; Hariharan, R; Fitzgerald, T; Zucker, D; Bunkow, M; Boore, J; Robinson, M; Sanders, K.; Crowley, J; Brown, T.; Hood, L.

- Cancer-Related Cognitive Impairment
- Fatigue
- Stress
- Arthralgias
- Weight and body composition changes
- Mucositis/colitis
- Neuropathy
- Depressive symptomatology

Treatment
Systemic chemotherapy (surgery, hormonal and/or biological agents, and irradiation also allowed)

Long-term survival

Dense, Dynamic Data Clouds
Clinical, genome, gut microbiome, metabolome, blood proteome, immune status, neuro-cognitive measurements, physiological, functional Imaging, ECOG performance status, Quality of Life and outcomes data

Actionable possibilities, quantitative assessment of interventions, discovery possibilities

Scientific Wellness
Personalized, preventative, and therapeutic, as well as behavioral interventions along with wellness coaching
Data Sharing through Oncology Precision Network (OPeN)

- **Founding Members**: Intermountain Healthcare, Providence St. Joseph Health, and Stanford Cancer Center
- **Goal**: to create a big data resource for clinical care and research using de-identified data.
- **Data shared**: genetic variants, tumor type/site, tumor stage, histology, tumor biomarkers, recommended and actual drug treatment, clinical outcomes, ethnicity/race, age and gender of the patient.
Data Sharing: Oncology Precision Network (OPeN)

- Multi-institutional collaboration
- Genomics data and outcomes
- 22 states, 190 hospitals
- Solves n=1 problem
Step 1: Source System Integration

Challenge: integrate data across multiple systems and labs
Step 2: Semantic Normalization Across Systems

• Choose a set of data elements that are clinically actionable and meaningful
  – Age, diagnosis, tumor histology, stage, genomic variants, treatments, outcomes

• Use vocabulary standards:
  – lung adenocarcinoma vs NSCLC: adenocarcinoma
  – KRAS G12D vs KRAS_G12D vs KRASG12D

• Automate the normalization process after the schema and standards have been established
Step 3: Federated architecture resolves data ownership concerns

- Nightly Assembly of Pre-defined Data Subset
- Syapse
- Intermountain’s Syapse application instance
- Stanford’s Syapse application instance
- Providence’s Syapse application instance
- Syapse
- Syapse
- Syapse
- Intermountain Precision Genomics
- Stanford Medicine
- SWEDISH CANCER INSTITUTE
Step 4: Search data by clinical or molecular characteristics
Anticipated Reach of OPeN

>100,000 New Cancer Cases Per Year

>500 Oncologists

>200 Hospitals
Goals of Data-Sharing

• Provide clinicians with real-world, aggregated patient data to support clinical treatment decisions.

• Determine treatment outcomes based on molecular fingerprints.

• Research activities:
  – Identify novel response biomarkers
  – Rationalize tumor mutation burden status across NGS platforms
  – Hypothesis generation
GNS Identifies the Right Intervention for the Right Patient via Causal Data-Driven Models
GNS Healthcare Machine Learning from PMRP
Identify and Understand Optimal Treatments in Patients: Breast Cancer Pilot

Data from PMRP & Breast Registry: 100+ Breast Cancer Patients

Breast Registry Clinical Data
PMRP Clinical Data
PMRP Gene Panel Data

Identification and understanding of optimal treatments for better disease outcomes

Model Explorer User Interface
AACR Project GENIE is an international, multiphase, multiyear project that provides the “critical mass” of genomic and clinical data necessary to improve clinical decision making and catalyze new clinical and translational research.

GENIE will aggregate existing and ongoing genotyping efforts from the eight phase 1 project participants into a single registry and link these data to select clinical outcomes. The data are publicly available at aacr.org/genie/data.

- Dana-Farber Cancer Institute
- Institut Gustave Roussy, France
- Memorial Sloan Kettering Cancer Center
- The Netherlands Cancer Institute on behalf of the Center for Personalized Cancer Treatment, The Netherlands
- Princess Margaret Cancer Centre, Canada
- Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, Maryland
- University of Texas MD Anderson Cancer Center
- Vanderbilt-Ingram Cancer Center

The GENIE registry is a tool that can be used in many ways:

- To confirm or refute that mutation X or mutations X, Y, and Z predict patient response to drug A or that the patient’s disease is likely to do better or worse over time.
- Drug B is approved for patients with mutation Y1. The GENIE registry indicates that patients with mutation Y2 can also be successfully treated with drug B.
- Drug C is approved for lung cancer patients with mutation W. The GENIE registry indicates that many blood cancers, colorectal cancers, and stomach cancers also have mutation W.

- Novel disease-causing proteins could be identified and become new drug targets.
- Novel mutation signatures could be uncovered that predict drug sensitivity or patient outcomes.
- New clinical trial(s) are opened to test drug C in blood, colorectal, and stomach cancers.

- Enough blood, colorectal, or stomach cancer patients in the GENIE data set have already been treated with drug C, so that it is an effective treatment for these patients.

The GENIE registry could provide the evidence necessary to support reimbursement for next-generation sequencing by payers, opening this technology to all patients.

Lessons learned from the assembly and operation of GENIE could benefit other global consortia and vice versa.
AACR Project GENIE Participants

Founding Consortium Participants

- Dana-Farber Cancer Institute, Boston, Massachusetts
- Gustave Roussy Cancer Campus, Paris-Villejuif, France
- The Netherlands Cancer Institute, Amsterdam, on behalf of the Center for Personalized Cancer Treatment, Utrecht, The Netherlands
- Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, Maryland
- Memorial Sloan Kettering Cancer Center, New York
- Princess Margaret Cancer Centre, Toronto, Ontario, Canada
- University of Texas MD Anderson Cancer Center, Houston, Texas
- Vanderbilt-Ingram Cancer Center, Nashville, Tennessee
Future Vision of Personalized Medicine

Cancer Patients

Targeted Population – Ph. I Candidates / Selected Populations (e.g., refractory disease, CNS)

Genome Sequencing (Clinical)

Biologic Profiling

Seattle Molecular Profiling Collaborative (CLIA/CAP/Research)

- Dense and Dynamic Personal Data Clouds
- Modeling Tumor Micro Env.
- Single Cell Analysis
- Analytics - Machine Learning/Bioinformatics/Decision Support/Statistics/Value Analysis

Biobank

High throughput screening

Ph. I - IV

Ph. I /N-of-One

Integrating Translational Research into Clinical Care

Next Gen of Clinical Trials Platform
Clinical Trials – Challenges in the Era of Personalized Medicine

Population Level
- Assess clinical trial feasibility in a given population
- Develop agile research infrastructure to accommodate evolving clinical trials network/design
- Screen and track status of every patient for clinical trial eligibility
- Provide access to all eligible patients in diverse populations

Patient Level
- Identify, integrate and prioritize clinical trial options available within the system, regionally and nationally, at point of care
- Screen patients against numerous and complex eligibility criteria
- Support patient education and engagement
- Keep treatment options updated throughout continuum of care
Challenges for Precision Medicine (In Ascending order)

• Cost and access to genomic testing.
• Cost and access to indicated therapies.
• Lack of actionable gene alterations.
• Education of all stakeholders.
• Patient expectations.
• Complexity of interpretation of data.
• Access to big data solutions.
• Expansion of physicians’ comfort zone.
Challenges to Data Inter-Operability and Sharing

- Diverse informatics platforms, for clinical, research and administrative applications.
- Varying nomenclature for given clinical and scientific data elements.
- Data security and privacy issues, to include HIPPA compliance.
- Data quality, to include arbitrating differences between multiple data sources for the same data elements.

(continued)
Challenges to Data Inter-Operability and Sharing

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• Evolving technologies and evidence base.
• Continued need for “manual” curation and abstracting of data.
• Cost and reimbursement.
# SCI PMRP TEAM

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Questions

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