About the Team Master’s Project

The Team Master’s Project (TMP) at Keck Graduate Institute (KGI) is a degree requirement and capstone activity for students in the Master of Business and Science (MBS) program at KGI. In accordance with KGI’s mission of translating the potential of the life sciences into practice, the TMP offers a rigorous and experiential learning opportunity which immerses students in the type of work many will pursue after graduation. TMPs are supported by interdisciplinary teams made up of three to six students who work with sponsoring companies to address real world company objectives.

Replacing the traditional master’s thesis work found in standard programs, these projects provide students with the opportunity to apply their marketing, business, financial, and science training to state-of-the-art corporate challenges. Importantly, our teams are advised by both KGI faculty and expert industrial liaisons to assure that academic rigor is paired with pragmatic focus. Members of TMP teams also include other KGI students in our postbac programs, Master of Engineering in Biopharmaceutical Processing, Master of Science in Applied Life Sciences, or Master of Science in Translational Medicine programs, as well as undergraduate students from The Claremont Colleges.

TMP activities emphasize problem-solving, project management, new business opportunity, productive teamwork, and effective communications skills that will be critically important to KGI graduates as they pursue careers in the applied life sciences industries. Representing about 35 percent of a student’s final year of academic work, these contract research projects are designed to produce valuable deliverables for the sponsoring companies.

Learn more about TMP by visiting kgi.edu/tmp
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3M TMP Marketing Research on Downstream Technologies for Manufacturing of Biopharmaceutical Products.

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Corporate Liason . . . . . . . . . . . . Nick Berthelsen

Faculty Advisors . . . . . . . . . . . . Angelika Niemz, Scott Motyka

The 3MTM Team Masters Project (TMP) team plans to continue working with 3M’s Separation and Purification Sciences Division (SPSD) focusing on voice-of-customer (VOC) feedback related to what drives the strategy behind the buying process of new and emerging technologies. This spring semester project is an extension of the data obtained during the fall semester of 2019 and will be completed by the beginning of May 2020.

For the second half of this TMP, SPSD is interested in content marketing regarding not only what resources customers want to see, such as white papers and other publications, but also what content regarding emerging technologies is sought out. To acquire data for this study, we plan to collect data from within the downstream manufacturing department of life science companies or CMOs.

The scope of this project is to evaluate SPSDs digital marketing impact on current and potential customers. The study plan is to design a Qualtrics survey and corresponding script to survey professionals working within the downstream process of manufacturing mAbs on a commercial scale, although emerging companies are also being evaluated. Although Qualtrics has a report and analysis features, the team plans to meet to interpret and measure the relevance of this data upon meeting with the corporate liaison. Analysis of the information obtained hopes to shed light on biopharmaceutical industry’s preferences for digital social-media content, as well as other formats, such as databases, white papers, and marketing content distributed at trade shows, conferences and seminars. 3M plans to use the results of the TMP analysis to improve their digital and content marketing strategy and find efficient methods to best communicate news and emerging technology in bioprocessing.
Enabling Amgen’s Operational Team for Long-Term Strategic Manufacturing and Analytical Scenario Analyses

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Corporate Liaisons ........ Pratik Ahuja, Leslie Maurer, Ceylan Undey

Faculty Advisor ............ Joel West

Founded in 1983, Amgen is one of the largest independent biotechnology companies in the world. The company’s primary goal is to serve patients by focusing on diseases with high-unmet medical needs. Currently, Amgen has 11 sites and more than 40 contract sites around the world to supply demand for 21-marketed products.

The goal of this year’s TMP project is to create a model to forecast demand and required capacity for Amgen’s drug substance and drug product facilities. The team will be focusing on creating an excel model based on Amgen’s current state of Thousand Oaks’, Massachusetts’, and Rhode Island’s’ capacity thresholds while forecasting clinical and commercial demand requirements for these plants.
Amgen is a biotechnology company specializing in developing and manufacturing biologic and biosimilar medicines. They have been involved in the biosimilars market since 2011. In 2018, Amgen had global revenues of $23.75 billion. They have expertise in developing biologic medicines to treat oncology, inflammation, and cardiovascular diseases.

Amgen would like to successfully continue breaking into the biosimilars market, providing additional treatment options for biologic medicines. Amgen hopes to better understand the future market conditions for biosimilars. Through this Team Master’s Project (TMP), Amgen hopes to gain an external perspective on specific questions to help inform how to navigate the highly competitive biosimilar market place of the future.

To provide the external perspective, the KGI TMP team has assessed the strengths, weaknesses, opportunities, and challenges for three undisclosed biosimilars in Amgen’s pipeline. Feeding into this overarching deliverable the team has completed in depth secondary research to analyze the impact of new molecular entities and competing biosimilars for each of the three pipeline assets. Additionally, the team has completed a probability of technical and regulatory success (PTRS) commercial viability framework for each molecule which will be used annually for objective assessment of each pipeline asset’s PTRS within the fast evolving biosimilars marketplace. From the insights gained through secondary research and analysis of the molecules and corresponding markets, the KGI team also provided external point of view on potential key swing factors affecting the U.S. biosimilars market as well as few recommendations for novel lifecycle management strategies for assets in the Amgen’s biosimilars pipeline asset.
Assessment of TransCon Technology Application and Market Viability for Oncology Indications and Other Disease Areas

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Corporate Liaisons. .......... Mary Metz, Katherine Wang

Faculty Advisor .............. Jenny Darroch

Cancer is the second leading cause of death globally, representing a widespread unmet need for effective treatments. Additionally, many rare diseases, such as growth hormone deficiency, hypoparathyroidism, and achondroplasia lack sufficient treatment alternatives. As the burden of these diseases continues to grow globally, more pioneering treatment options are increasingly necessary. Ascendis Pharma (Ascendis) understands the urgency behind this global call to action for new therapeutic treatments for cancer and rare diseases in order to address the unmet needs of these vulnerable patient populations worldwide.

Ascendis Pharma is quickly becoming a leader in new cutting-edge therapies using its innovative TransCon technology platform. Ascendis Pharma’s TransCon platform enables the sustained release of a drug in a controlled and predictable manner, thereby prolonging a drug’s therapeutic effect in the body through an increased half-life. TransCon may also provide safer delivery of highly potent drugs that otherwise have significant systemic toxicity. Using this platform, Ascendis strives to make a meaningful impact in patients’ lives.

Ascendis Pharma is currently developing product candidates in two therapeutic areas: endocrinology rare diseases and oncology. All three endocrinology rare disease candidates are in clinical trials and show great promise and the exciting oncology candidates are still in preclinical development. KGI was selected to assist Ascendis Pharma as it continues to develop new compounds and target new disease areas. The Ascendis Pharma Team Master’s Project has worked to identify and prioritize the top five indications to pursue in oncology for a new TransCon product and assess top indications in a new disease area for one of Ascendis Pharma’s existing TransCon therapeutics.
Development of the Master Data Management and Governance Roadmap

Students. .................. Taylor Hughes, John T. Fly III, Karanvir Grewal, Benjamin Nittayo, Harsha Ohri, Santiago Patiño, Muhammad Shamim

Corporate Liaisons. ........ Jeff Ketelhut, Daniel Lee, Judy McHugh

Faculty Advisor ............ Jay Chok

Atara Biotherapeutics is a leading off-the-shelf, allogeneic T-cell immunotherapy company that is developing novel treatments for patients with severe and life-threatening diseases like cancer, autoimmune and viral diseases. Founded in 2012, Atara is a development-stage company with a unique platform to create off-the-shelf allogeneic T-cell therapies. Currently, its main locations are in South San Francisco, CA (Corporate Headquarters), and Thousand Oaks, CA (R&D and Manufacturing site).

As an organization develops from a small start-up to a large corporation, the importance of correctly recording, managing, and governing data becomes increasingly paramount. It is critical to address these procedures because proper management of master data can enhance GMP compliance. Currently, Atara is looking into improving their already functional data flow and governance within and between the systems used by different departments.

Therefore, the team’s objectives for this project are to gather data from different systems used in-house through interviews with subject matter experts, recognize the master data present in the different systems, bridge information gaps between systems, and identify the current system’s processes and governance body. Ultimately, after analyzing the data obtained, the team will attempt to utilize in-house capabilities to propose a solution for Atara’s data management and governance development.
BioMarin Pharmaceutical Inc. is a world leader in the development and commercialization of therapies for rare genetic diseases. With continued and rapid growth, BioMarin has initiated business transformation processes to improve efficiencies in their end to end Order to Cash (OTC) process. One focal point for several of these transformation efforts is Customer Master Data (CMD). Currently, CMD at BioMarin does not adequately address the unique complexity of its products and requires additional scalability to drive future growth.

The KGI team was tasked with generating four deliverables: industry best practices, an immediate-term solution, a long-term solution, and governance processes. The best practices document summarized the group’s primary and secondary research findings on generally accepted CMD practices in the pharmaceutical industry. The immediate-term solution proposed structural data changes that address CMD complexity within the current systems landscape. The long-term solution provided several potential options to BioMarin for addressing long-term CMD complexity, each of which enables scalable growth and OTC process efficiency. Finally, the governance processes delineated clear responsibilities within CMD processes and detailed actions that are necessary for actionable CMD cross-functionally.

With these four deliverables, the team will enable BioMarin to improve CMD structure and management. This will lead to an increase in overall OTC efficiency by supporting transactions with accurate data, standardized execution, clear reporting, and reduced risk.
Boehringer Ingelheim (BI) is a privately-owned pharmaceutical company founded in 1885 by Albert Boehringer. The company started with 28 employees and grew into a global enterprise that today is among one of the top 20 pharmaceutical companies in the world. BI has a pipeline that ranges from drugs for humans to veterinary-use therapeutics. BI is a world-leading biopharmaceutical contract manufacturer that offers its clients distinct contract development and manufacturing services, ranging the entire production technology chain.

BI must develop optimal processes that shorten product-manufacturing time and assure quality to meet the product’s critical quality attributes. Media preparation is one of the key elements that can establish an efficient process. Not only does the composition of the media play a relevant role, but proper homogenization and optimal mixing time are also crucial determinants. Computational fluid dynamics (CFD) can be a very useful tool when modeling media preparation, as it permits tank characterization that may not be achieved empirically with such precision and detail. Additionally, CFD can save resources and time as it provides a deep analysis using mainly computational power.

The goal of this Team Master’s Project is to characterize media preparation tanks using CFD simulations. Four different tanks will be assessed, and, within each tank, parameters like volume, agitation speed, impeller type and impeller position will be taken into consideration. CFD will be used as a tool to obtain mixing time and power number. Velocity profile and optimization suggestions will also be included.
Investigate and Analyze Continuous Processing and the Implementation of this Technology in the Pharma industry

Students ................ Ayman Abdelaaty, Terezie Cernosek, Jialiang Huang, Vanely Ponce, Angel Chuta Salazar

Corporate Liaisons ........ Raj Desai, Joseph Pate, William Wessel

Faculty Advisor ............ Sue Behrens

Catalent Pharma Solutions is a Contract Development and Manufacturing Organization (CDMO) that provides services to support the biopharmaceutical industry. They are a global leader in the development of biologic drugs as well as manufacturing services; therefore, it is crucial that they remain up to date with the latest technology to address any potential process bottlenecks. With multiple sites across North America and Europe, Catalent strives to utilize the latest technologies to offer the best services in development, analytics, and manufacturing while focusing on quality and efficiency.

The Catalent Team Master’s Project (TMP) is utilizing the Superpro Designer Software to model their batch manufacturing process for monoclonal antibody production as a baseline. The team will expand the simulations to evaluate the potential opportunities for continuous manufacturing processing. The scope of the project entails different scenarios, with three simulations each, involving combinations of fed-batch or perfusion upstream and single column or multi-column downstream. Alongside the simulations, the economics of these scenarios will be assessed using the cost of materials and labor, to provide Catalent and its clients a better insight on the benefits and challenges associated with implementing a continuous manufacturing process.

The TMP group maintains regular communication with our corporate liaisons as the simulations are being built to verify the inputs align with Catalent’s current manufacturing process. In addition, the data generated by the model is reviewed with our liaisons to determine the feasibility of implementing a continuous process. Once completed, these models will allow Catalent to further explore the implementation of continuous manufacturing operations in their facilities and offer the option to clients as it increases production, efficiency, and quality.
Research into the Future of the Supply Chain over the Next Five Years

Students ................. Maria Angulo, Courtney Boudreaux, Cathy Pham, Crystal Salinas, Erik Wehse, Yutong Zhong

Corporate Liaisons ........... Alejandro Jatem, Paul deRoulhac

Faculty Advisor ............. Ed Arnheiter

Genentech is a biotechnology company dedicated to pursuing groundbreaking science to discover and develop medicines for people with serious and life-threatening diseases. As a member of the Roche group, their work includes the first targeted antibody for cancer and the first medicine for primary progressive multiple sclerosis.

The Digital Supply Chain Team is evaluating how to accelerate the transformation of the supply chain across the organization through the implementation of emerging technologies in order to connect patients to medicines and innovative solutions faster. These technologies include advanced analytics, internet of things, advanced robotics, edge computing, augmented reality/virtual reality technologies, and blockchain. The implementation of these new digital tools will benefit supply chain capabilities over the years to come.

The Genentech Team Master’s Project team was tasked with researching the supply chain of the future, and where the leading supply chain standards will be within five years. To accomplish this, the team identified leaders in supply chain and conducted interviews with Key Opinion Leaders. The KGI team then analyzed the primary research and made recommendations to Genentech to assist with their improvement of their company’s supply chain. The key deliverable included a report documenting these findings and recommendations and comprehensive presentation showcasing what the KGI team achieved.
TS Project and Lab Management Plan for Gilead Engagement

Students. ............... Jake Berber, Nina Kar, Michelle Nguyen, Om Patel, Steven Pham, Swati Thakur

Corporate Liason. ............. Thomas Upton

Faculty Advisor ............... Sukumarakurup Krishnakumar

Gilead Sciences was founded in 1987 in Foster City, CA. In the 30 years since its inception, Gilead has expanded nationally and internationally with over 27 approved and marketed therapeutics.

The Technical Services (TS) department at Gilead is responsible for various services that are critical to the development and the support of Gilead product production. TS supports various departments within Gilead by providing expertise in many different functions including process development, formulation development, particulate matter identification/forensics, analytical method development, and material compatibility studies. However, the TS department and their capabilities have not been extensively realized across the company. As a result, multiple departments use external organizations to execute some of the same services.

Our project focuses on increasing the visibility of TS’s current in-house capabilities across Gilead. This is broken down into two overarching objectives: Laboratory management based on current “good practice” quality guidelines and increasing TS engagement across Gilead. For the Lab management objective, a gap analysis was conducted to assess the current state of the department before employing engagement strategies. Relative to TS engagement across Gilead, the department website will be fully revamped and a full-scale plan for channels of communication have been developed. Upon completion of the project, Technical Services can leverage current and prospective communication channels to increase their engagement across Gilead.
Gilead is a global biopharmaceutical company focused on the discovery, development, and commercialization of innovative therapeutics in areas of unmet medical need. From the time it was founded in 1987, Gilead has developed a strong portfolio of antiviral drugs to treat diseases such as HIV, hepatitis B, hepatitis C, and influenza. The Team Master’s Project (TMP) team has been working with the Gilead Oceanside site, which specializes in developing and manufacturing therapeutic biologics.

Gilead is evaluating external partnership options for Cell Line Development (CLD) capabilities. To address this business need, the TMP team was tasked with mapping the current industrial landscape for contract organizations in line with Gilead’s criteria. The first step to achieve this goal was to build an overall understanding through primary research on the scientific innovations and operational capabilities in the CLD space. Secondary research was then performed to develop a contract organization database by means of survey and interview with subject matter experts from contract organizations and end users. Ultimately, the team analyzed the data to recommend contract organizations that Gilead could partner with for CLD activities.
Hologic, Inc. is a leading innovator in women’s health, currently possessing 15% of the molecular diagnostics (MDx) market. Molecular Diagnostics is becoming a competitive industry with fierce customer loyalty resulting in long platform life. To increase its market position, Hologic seeks to venture into low-volume “Point of Care” (POC) diagnostic platforms, as well as offer an increased breadth of tests to break into new disease areas such as acute care and Virology.

The objective of this year’s KGI Team Master’s Project was to evaluate the POC market for segments of interest to determine whether or not Hologic should enter the POC market, and in what capacity. The KGI team used secondary data to establish a view of the current POC market and its device usage compared to Hologic’s systems. The team then developed an inquisitive primary interview guide to determine the proclivity of customers to consolidate platforms for POC and virology testing. By analyzing the results from this questionnaire and previous data, the team’s final goal was to deliver a final assessment and consultation on potential market entry.
Addressing Manufacturing Inefficiencies within Calibration and Internal Quality Control

Students ................ Jai Bhakta, Seunghee Erin Kim, Eun Ae Park, Hanna Shiferaw, Derrick Sy, Maria Wu

Corporate Liaisons ........ Richard Velasco, Trinidad Mireles, Crystal Achenbach

Faculty Advisor ........... Jim Sterling

Originally founded in 1949, Medtronic (MDT) is now a world leader in the development, manufacturing, and sale of high-quality medical devices. By maintaining its core values of “alleviating pain, restoring health, and extending life”, MDT is able to positively contribute to the global community through its products.

Medtronic tasked the team with addressing inefficiencies in their manufacturing process, pertaining to the calibration of assets and raw material inspections.

Calibration: In the calibration department, the team created a baseline of cost savings within the calibrated assets and analyzed additional cost-saving methods. An updated database of relevant calibrated assets was created to reassign assets with respect to their calibration needs and final product impact. Then, the team determined if assets had unnecessary planned calibrations in order to reduce overall calibration frequencies. Finally, the cost of unplanned calibrations was calculated, then used to evaluate the effects of the out-of-tolerance assets and production line moves.

Inspection Process: Within the Internal Quality Control department (IQC), the team was assigned to create a dashboard displaying metrics that will promote transparency and assist in the reduction of raw material inspection time. In order to accomplish this task, the team analyzed the current inspection process, researched common inventory software, and assisted in the dashboard design and implementation.

With the completion of these projects, the team increased both efficiency and cost savings for Medtronic’s Neurovascular Manufacturing department.
Developing and Evaluating Pharmaceutical Lifecycle Management Strategies for an Approved Product for Inflammatory Skin Diseases

**Students.** Isaiah Alba, Gabriella Mihana Alden, Amelia Huynh, Parizad Panthaki, Joselin Vizcaya, Maxine Yang

**Corporate Liaisons.** Bonnie Vlahos, John Werth

**Faculty Advisor.** Alan Rothfeld

Pfizer is a leading biopharmaceutical company with a strong foundation in biotechnology. Grounded in a powerful purpose, breakthroughs that change patients’ lives, Pfizer translates advanced science and technologies into therapies that matter for patients in need. Focusing on pharmaceutical development and innovation, their worldwide research and development is rooted in five disease areas: oncology, internal medicine, vaccines, inflammation, and rare disease.

One therapeutic focus area for Pfizer within their inflammation disease area is medical dermatology, which includes a variety of skin diseases known as inflammatory dermatoses. One of Pfizer’s currently approved topical products, Crisaborole, has proven to be effective and is approved for the treatment of mild to moderate topic dermatitis (AD), commonly known as eczema.

As directed by Pfizer’s Clinical Development Global Innovative Business Unit, our Team Master’s Project (TMP) was responsible for evaluating opportunities and developing the framework for two lifecycle proposals for Crisaborole. The team provided a comprehensive assessment of inflammatory skin and autoimmune diseases, along with their respective treatment landscapes and developed an objective scoring tool to analyze and rank 25 diseases. This tool was the foundation for further investigation into clinical trial potential, which led to the team’s recommendations to Pfizer.
Gene Therapy Commercial Site Readiness “Super Analog”

Students. ................. Alec Botros, James Cross, Christian Dávila, Quinn Levin, Kristi Low, Neha Mohindroo

Corporate Liasons. ........ Allicyn Aubut, Tino Quintero, Emily Regan

Faculty Advisor ............. Kenneth Gruys

Sarepta is leading a revolution in precision genetic medicine—every day is an opportunity to change the lives of people living with rare disease. The company has built an impressive position in Duchenne muscular dystrophy (DMD) and in gene therapies for limb-girdle muscular dystrophies (LGMDs), mucopolysaccharidosis Type IIIA, Charcot-Marie-Tooth (CMT), and other CNS-related disorders, with more than 40 programs in various stages of development. The Company’s programs and research focus span several therapeutic modalities, including RNA, gene therapy and gene editing.

Sarepta is developing a commercial site readiness strategy for the potential launch of their in-vivo micro-dystrophin gene therapy product for DMD (SRP-9001). The product is a novel therapy for the DMD population and will disrupt current treatment pathways; clinical protocols and institutional processes will need to change so institutions can provide this therapy. In order to ensure high quality support and a smooth launch, the Sarepta Team Master’s Project (TMP) team was tasked with determining a “super analog” for Sarepta to consider as they evolve their site readiness strategy. This involved performing analysis on innovative treatments, disruptive products, one-time procedures, digital applications, and centers of excellence. In identifying and researching different models, the TMP team summarized common pain points, best practices, and innovative solutions to provide suggestions for all steps in the patient journey, taking into consideration multiple participants involved in gene therapy administration (patient, caregiver, provider and institution). Completion of this project has provided Sarepta with important information to holistically support the DMD community and solve challenges of gene therapy commercialization.
Media Evaluation and Omics Analysis of CHO Cells


Corporate Liason. ............ Jeraldine Mendoza

Faculty Advisor .............. Aster Escalante

Thermo Fisher Scientific is an American biotechnology product development company that was founded in 2006. Thermo Fisher provides many different technologies including materials for antibody applications, single-use bioprocessing, laboratory equipment, cell culture media, and more. The goal of this laboratory-based project was to assess a panel of six non-commercially available media and two commercially available media with Keck Graduate Institute’s Chinese Hamster Ovary (CHO) cell bank in order to compare cell culture performance across different media formulations. To complete this experiment, 3 CHO cell lines (CHO-S, CHO-K1 and CHO-DG44) were directly adapted to the provided media. A working cell bank was created from each cell-media combination for use in 14-day fed batch studies, which was followed by an analysis of the acquired data to determine the optimal media for each cell line. Cell culture conditions and cell growth profiles were monitored using in-house KGI equipment. Additionally, the team acquired proteomics and metabolomics samples to send to Thermo Fisher. Following the completion of shake flask studies, the optimal conditions were assessed in 3L bioreactors. The completion of this project has provided Thermo Fisher with an unbiased assessment of each provided media using KGI’s CHO cell lines.
Dynamic Operations Model for Commercial Launch of Novel Drug

Students: Kaushik Amancherla, Sharif Kombo, Ralston Mataki, Kathrine Parga, Maria Rivera, Karthika Thangaraj

Corporate Liaison: Doug Rich

Faculty Advisor: Jim Osborne

Unity Biotechnology, Inc. (UNITY) is a biotechnology company based out of San Francisco, CA. Founded in 2011, UNITY is developing therapeutics to extend health span by slowing, halting, or reversing diseases of aging.

UBX0101 is currently being evaluated for the treatment of musculoskeletal disease, with an initial focus on osteoarthritis (OA) of the knee. This project will encompass performing a market opportunity analysis of the OA market by understanding the addressable market, current treatments, healthcare processes, FDA’s approval process, competitors, and potential differentiation of UBX0101. The overall goal is to have sufficient consideration of various factors that contribute to market demand, adoption rate, and manufacturing supply strategies. The team will ultimately create a program that accounts for all these stakeholders and develop a dynamic demand model to support the commercialization of UBX0101.
Keck Graduate Institute would like to thank all our sponsors for their generous support of the Team Master’s Project.

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KECK GRADUATE INSTITUTE (KGI) was founded in 1997 as the first higher education institution in the United States dedicated exclusively to education and research related to the applied life sciences. KGI offers innovative postgraduate degrees and certificates that integrate life and health sciences, business, pharmacy, engineering, and genetics, with a focus on industry projects, hands-on industry experiences, and team collaborations.

A member of the Claremont Colleges, KGI employs an entrepreneurial approach and industry connections that provide pathways for students to become leaders within healthcare and the applied life sciences. KGI consists of four schools: The Henry E. Riggs School of Applied Life Sciences, the School of Medicine, the School of Pharmacy and Health Sciences, and the Minerva Schools at KGI.

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