

# 2021 Sustainability Accounting Standards Board (SASB) Index

Topic	Metric	Category	Unit of Measure	SASB Code	Disclosure
SASB Healthcare: Biotechnology Pharmaceuticals (HC:BP)					
Safety of Clinical Trial Participants	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials	Discussion & Analysis	n/a	HC-BP-210a.1	<p>Catalyst leverages the mechanisms described in our Standard Operating Procedures specific to vendor qualification and vendor management to ensure that all vendors involved in clinical trial activities meet the requirements outlined in relevant national and international standards such as the ICH guidelines, FDA regulations pertaining to Good Clinical Practices (GCP), all trial subject protections from the Helsinki Declaration, as well as other comparable resources, references, and requirements. Catalyst also leverages Standard Operating Procedures that govern our vendor qualification, related requirements and tracking, our GxP audit planning and execution (specifically including manufacturing and clinical trial quality audits), and our overall quality management plan. Collectively, our Standard Operating Procedures describe a set of standards for quality and safety, as well as a process to monitor and initiate corrective actions, as necessary.</p> <p>In 2021, Catalyst's only clinical trial activities were conducted in the U.S. CROs are used in a very limited fashion in the U.S., primarily for single tasks within the trial management process such as identifying sites, setting up a trial master file, and performing statistical analysis. Catalyst directly manages all other aspects of the study.</p> <p>The process of obtaining informed consent from participants in clinical trials is specific to the study and site in focus. We provide a template for Informed Consent Forms (ICF) for each study in addition to the detailed protocol for the study. Note, each ICF is developed in accordance with each site's requirements and their Institutional Review Board (IRB). Further, we ensure that the minimal elements of informed consent are contained in their version, and we complete site audits to confirm documentation, verify that the necessary steps are being followed, and ensure that the ICFs at each site are up to date with current study information.</p> <p><i>For additional information:</i></p> <p><u><a href="#">Catalyst Path to Approval</a></u></p>

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SASB Healthcare: Biotechnology Pharmaceuticals (HC:BP)					
<b>Safety of Clinical Trial Participants</b>	Number of FDA Sponsor Inspections related to clinical trial management and pharmacovigilance that resulted in: (1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI)	Quantitative	Number	HC-BP-210a.2	In 2021, there were no FDA Sponsor Inspections, or any inspections by other regulatory agencies related to clinical trial management and pharmacovigilance. Therefore, there were no findings that resulted in a classification of Voluntary Action Indicated (VAI) or Official Action Indicated (OAI).
<b>Safety of Clinical Trial Participants</b>	Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries	Quantitative	Reporting currency	HC-BP-210a.3	Catalyst has not been involved in any legal proceedings associated with clinical trials in any countries. As a result, we have not incurred any monetary losses in 2021.
<b>Access to Medicines</b>	Description of actions and initiatives to promote access to health care products for priority diseases and in priority countries as defined by the Access to Medicine Index	Discussion & Analysis	n/a	HC-BP-240a.1	<p>Catalyst currently only has rights to develop, commercialize, and distribute our sole product in the U.S., Mexico, Canada, and Japan, none of which are considered high priority countries as defined by the Access to Medicine Index. Note, our product is sub-licensed out to other entities in Canada and Japan who control distribution and marketing activities.</p> <p>Additionally, our product is currently only approved to treat Lambert-Eaton Myasthenic Syndrome ("LEMS"), which is not a high priority disease as defined by the Access to Medicine Index.</p> <p>However, at Catalyst, we believe every patient should have access to necessary medication. We are committed to efforts to make our products available to all patients regardless of their ability to pay. We have implemented an Expanded Access Program (EAP) that we created for our lead product, FIRDAPSE®. Through the EAP, any patient in the U.S., within the scope of allowed diagnoses, may access the product at no charge prior to FDA approval.</p>

					<p>We are also working with insurance companies to help optimize coverage for our FDA-approved products, as well as developing a support program for privately insured patients in need. For those patients who may be underinsured or uninsured and who meet financial need qualifications, we provide our product free of charge.</p> <p>Catalyst has been a long-time supporter of various charities through donations and employee volunteer efforts, including Medical Students in Action, which supports medical students traveling to countries with urgent health care needs to use their developing skills; Camillus House, which provides humanitarian services to the indigent and homeless populations of Miami-Dade County, Florida; and The Woody Foundation, which works to transform the quality of life of those living with paralysis and their caregivers, among many others.</p> <p><i>For additional information:</i></p> <p><u><a href="#">Catalyst Responsibility Webpage</a></u></p>
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SASB Healthcare: Biotechnology Pharmaceuticals (HC:BP)					
Access to Medicines	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP)	Discussion & Analysis	n/a	HC-BP-240a.2	Catalyst does not have a list of products authorized for sale and available on the WHO List of Prequalified Medicinal Products given Catalyst manufactures and sells one product - FIRDAPSE® - for an ultra-orphan population and only holds distribution rights for the product in the U.S. and Mexico. The distribution and marketing rights for the product in Canada and Japan have been sublicensed to other entities.
Affordability & Pricing	Number of settlements of Abbreviated New Drug Application (ANDA) litigation that involved payments and/or provisions to delay bringing an authorized generic product to market for a defined time period	Quantitative	Number	HC-BP-240b.1	The FDA is not accepting Abbreviated New Drug Application's (ANDAs) for Catalyst's product. As such, we have not had to address Hatch-Waxman challenges to ANDAs to date.
Affordability & Pricing	Percentage change in: (1) average list price and (2) average net price across U.S. product portfolio compared to previous year	Quantitative	Percentage (%)	HC-BP-240b.2	In 2021, the increase in list price for FIRDAPSE® (our only product) was less than 5%. The total increase in list price was also less than 5% in 2020.
Affordability & Pricing	Percentage change in: (1) list price and (2) net price of product with largest increase compared to previous year	Quantitative	Percentage (%)	HC-BP-240b.3	In 2021, the increase in list price for FIRDAPSE® (our only product) was less than 5%. The total increase in list price was also less than 5% in 2020.

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Drug Safety	List of products listed in the Food and Drug Administration's (FDA) MedWatch Safety Alerts for Human Medical Products database	Discussion & Analysis	n/a	HC-BP-250a.1	During 2021 and at the time of reporting, no drugs or products developed by Catalyst were listed in the FDA's MedWatch Safety Alerts for Human Medical Products database. Additionally, the FDA staff in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) have not identified any potential safety issues in Catalyst drugs and products.
Drug Safety	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System	Quantitative	Number	HC-BP-250a.2	<p>In 2021, there were 32 fatalities in the U.S. and 1 fatality in Canada among FIRDAPSE® patients identified by Catalyst. Out of the 33 total fatalities, there was only one case with possible attribution to FIRDAPSE®. None of the remaining cases were determined to be attributable to FIRDAPSE®. Note, among patients with LEMS, there is a high prevalence of cancer comorbidities (~50%), as well as other autoimmune comorbidities. Additionally, this data is from reports received and reviewed by Catalyst and there may be discrepancies with FDA reported data due to the potential for duplicate reports (one to FDA and a separate one to Catalyst subsequently reported to the FDA) and for reports received by other manufacturers for patients who are also on FIRDAPSE® but which are not reported to Catalyst.</p> <p><i>For additional information:</i></p> <p><u><a href="#">10-K, pg. 8</a></u></p>

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SASB Healthcare: Biotechnology Pharmaceuticals (HC:BP)					
Drug Safety	Number of recalls issued, total units recalled	Quantitative	Number	HC-BP-250a.3	<p>Catalyst has not been subject to any product recalls, including ones in non-U.S. markets and those not subject to FDA reporting.</p> <p>Through our restricted distribution system in the U.S. and our serialization system, Catalyst is able to identify the recipients of all products we manufacture and distribute for which we are listed as the recalling firm for the "Drugs" product type in FDA enforcement reports. A similar distribution system is used in Canada for the Catalyst product sold by our partner KYE Pharmaceuticals.</p> <p>In the case of recalls, Catalyst would disclose this occurrence per our standard disclosure requirements.</p>
Drug Safety	Total amount of product accepted for takeback, reuse, or disposal	Quantitative	Metric tons (t)	HC-BP-250a.4	<p>In the fall of 2021, Catalyst began participating as a member of the Pharmaceutical Product Stewardship Work Group (PPSWG) Drug Takeback Initiatives, whose mission is to provide infrastructure, guidance, and subject matter expertise to support member compliance and improve awareness of existing pharmaceutical disposal options. Given the recent initiation of these efforts, we are unable to provide the amount of unused product that was accepted through takeback initiatives in 2021. Looking ahead, we look forward to providing additional detail on this metric.</p> <p>In the rare instances in which product is returned to a Specialty Pharmacy by a patient, Catalyst will pay for the destruction of that product.</p> <p><i>For additional information:</i></p> <p><a href="#">PPSWG Webpage</a></p>

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SASB Healthcare: Biotechnology Pharmaceuticals (HC:BP)					
Drug Safety	Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP), by type	Quantitative	Number	HC-BP-250a.5	In 2021, no FDA enforcement actions or similar actions by any regulatory agencies were taken in response to violations of current Good Manufacturing Practices (cGMP).
Counterfeit Drugs	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting	Discussion & Analysis	n/a	HC-BP-260a.1	<p>Catalyst complies with all statutes and regulations related to serialization of product, traceability and preventing counterfeiting of pharmaceutical products to protect the safety and well-being of our patients.</p> <p>Catalyst is a member of GS1, which sets standards for unique product identifiers necessary for effective and workable international track and trace functionality for serialized prescription drugs. We utilize the TraceLink system for generating and managing serialization of our products at the individual package level. Each package unit and aggregate package unit (carton, case, pallet) is affixed with a barcode that details its serial number.</p> <p>The serial numbers are tracked through the distribution channel to facilitate identification through movement in the supply chain at the product level, from product release through dispensing to patients.</p> <p>Catalyst does not leverage RFID tagging technology given sales volume and the limited and restricted distribution model that is employed for FIRDAPSE®.</p> <p><i>For additional information:</i></p> <p><a href="#">Catalyst Responsibility Webpage</a></p> <p><a href="#">10-K, pg. 24</a></p>

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SASB Healthcare: Biotechnology Pharmaceuticals (HC:BP)					
Counterfeit Drugs	Discussion of process for alerting customers and business partners of potential or known risks associated with counterfeit products	Discussion & Analysis	n/a	HC-BP-260a.2	<p>Catalyst's internal policy on Suspected Products specifically outlines the steps Catalyst is to take to notify patients and business partners in the event a product is determined to be counterfeit or illegitimate. In the event Catalyst needs to issue a recall, we would disclose this occurrence per our standard disclosure requirements. Catalyst would promptly notify the appropriate regulatory agencies and all downstream trading partners of the recall within the legally required time horizon, and more urgently if safety issues are raised.</p> <p>Our Standard Operating Procedure also describes the processes for determining when to initiate a recall and for subsequent activities through termination of the recall.</p> <p>Catalyst supports the distribution of FIRDAPSE® in the United States through Catalyst Pathways®, our personalized treatment support program. Catalyst Pathways® provides enrolled patients with personalized treatment support, education, and guidance, supporting them through challenging dosing and titration regimens required to reach an effective therapeutic dose. Catalyst Pathways® also distributes FIRDAPSE® through a small group of exclusive specialty pharmacies, primarily AnovoRx Specialty Pharmacy. The low volume of distribution and limited patients – most of whom Catalyst is in contact with through the Catalyst Pathways® program – alongside our recommendation that purchases only be made from recognized and approved vendors and distributors significantly decreases the risk of counterfeit products.</p> <p><i>For additional information:</i></p> <p><u><a href="#">10-K, pg. 4</a></u></p>



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SASB Healthcare: Biotechnology Pharmaceuticals (HC:BP)					
Counterfeit Drugs	Number of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products	Quantitative	Number	HC-BP-260a.3	<p>In 2021, Catalyst had no actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products.</p> <p>Catalyst has a Standard Operating Procedure that describes the process for managing an investigation into a suspect or potentially counterfeit product, including when and how to alert the FDA or other regulatory agencies to any potential and/or confirmed counterfeit product.</p>
Ethical Marketing	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims	Quantitative	Reporting currency	HC-BP-270a.1	<p>In 2021, Catalyst had zero monetary losses or payments as a result of legal proceedings associated with false marketing claims.</p>

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SASB Healthcare: Biotechnology Pharmaceuticals (HC:BP)					
Ethical Marketing	Description of code of ethics governing promotion of off-label use of products	Discussion & Analysis	n/a	HC-BP-270a.2	<p>Catalyst is committed to fair and ethical conduct and compliance with the law. Our Code of Business Conduct and Ethics covers a wide range of business practices and issues for our employees and sets forth basic principles to provide further guidance and ensure adherence. Specifically, our Code of Business Conduct and Ethics includes provisions setting high standards specific to interactions with physicians and patients, professional conduct, and representation of clinical trial data, in addition to steps to take to avoid any potential misrepresentations of facts. All Medical Affairs and Commercial employees must participate in an initial training of the Code of Business Conduct and Ethics – which explicitly covers labeling and promotion – in addition to routine follow-up trainings.</p> <p>Through Catalyst's compliance program, operated by the Chief Compliance Officer, relevant training is provided to all employees based on roles and responsibilities. The Chief Compliance Officer is also head of the Legal, Medical, and Regulatory Review Committee that reviews and approves all relevant material to be used in the field to be sure that it is all on-label, well substantiated, and in compliance with all regulatory requires prior to filing any necessary materials with the FDA.</p> <p>In addition, our Compliance function conducts monitoring of field activities both in-person and through recorded reviews to ensure compliance with the Code of Business Conduct and Ethics. In the event a potential violation is detected, an investigation would be launched to determine if any violations occurred. In the case of violations, Catalyst would institute corrective and/or disciplinary actions.</p> <p><i>For additional information:</i></p> <p><u><a href="#">Code of Business Conduct and Ethics</a></u></p> <p><u><a href="#">10-K, pg. 24 and pg. 40</a></u></p>

Topic	Metric	Category	Unit of Measure	SASB Code	Disclosure
SASB Healthcare: Biotechnology Pharmaceuticals (HC:BP)					
Employee Recruitment, Development & Retention	Discussion of talent recruitment and retention efforts for scientists and research and development personnel	Discussion & Analysis	n/a	HC-BP-330a.1	<p>Catalyst is committed to attracting and retaining top-tier talent across the industry. Our approach to recruitment and retention is uniform across all roles and activities within the company, though occasionally individual hiring needs may be prioritized based on needs of the business.</p> <p>We review our incentive structures on an annual basis to determine if they are adequately aligned with Company strategy and that they are equally attractive and compelling for all employees. We offer a comprehensive package of benefits, including a 401K with safe harbor match and a stock incentive plan for all eligible employees.</p> <p>Additionally, we reimburse employees for career development training such as CME, CPE, CLE, and other job-specific certifications and trainings.</p> <p><i>For additional information:</i></p> <p><u><a href="#">10-K, pg. 26</a></u></p>

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SASB Healthcare: Biotechnology Pharmaceuticals (HC:BP)					
Employee Recruitment, Development & Retention	(1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) midlevel managers, (c) professionals, and (d) all others	Quantitative	Rate	HC-BP-330a.2	<div><div>Professional Level<sup>1</sup></div><div>2021 Voluntary Turnover Rate</div><div>2021 Involuntary Turnover Rate</div><div>2021 Total Turnover Rate</div></div>
					<div>Executives</div> <div>0.0%</div> <div>0.0%</div> <div>0.0%</div>
					<div>Mid Level Managers</div> <div>8.0%</div> <div>8.0%</div> <div>16.0%</div>
					<div>Professionals</div> <div>5.8%</div> <div>2.9%</div> <div>8.7%</div>
					<div>Sales</div> <div>18.8%</div> <div>6.3%</div> <div>25.0%</div>
					<div>Administrative</div> <div>40.0%</div> <div>0.0%</div> <div>40.0%</div>
					<div>All Employees</div> <div>9.3%</div> <div>4.0%</div> <div>13.3%</div>
					<div>Professional Level<sup>1</sup></div> <div>Average 2021 Employee Headcount</div> <div>2021 Voluntary Turnover</div> <div>2021 Involuntary Turnover</div> <div>2021 Total Turnover</div>
					<div>Executives</div> <div>10.0</div> <div>0</div> <div>0</div> <div>0</div>
					<div>Mid Level Managers</div> <div>12.5</div> <div>1</div> <div>1</div> <div>2</div>
					<div>Professionals</div> <div>34.5</div> <div>2</div> <div>1</div> <div>3</div>
					<div>Sales</div> <div>16.0</div> <div>3</div> <div>1</div> <div>4</div>
					<div>Administrative</div> <div>2.5</div> <div>1</div> <div>0</div> <div>1</div>
					<div>All Employees</div> <div>75.5</div> <div>7</div> <div>3</div> <div>10</div>
					<sup>1</sup> All employees classified according to the U.S. Equal Employment Opportunity Commission EEO-1 <a href="#">Job Classification Guide</a>

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SASB Healthcare: Biotechnology Pharmaceuticals (HC:BP)					
Supply Chain Management	Percentage of (1) entity's facilities and (2) Tier I suppliers' facilities participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients	Quantitative	Percentage (%)	HC-BP-430a.1	<p>Given Catalyst does not own or operate any facilities, the percentage of our facilities participating in the Rx-360 Internal Supply Chain Consortium audit program is not relevant.</p> <p>However, 29% of our Tier 1 supplier facilities participate in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program.</p>
Business Ethics	Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery	Quantitative	Reporting currency	HC-BP-510a.1	In 2021, Catalyst had zero monetary losses as a result of legal proceedings associated with bribery and corruption.

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SASB Healthcare: Biotechnology Pharmaceuticals (HC:BP)					
Business Ethics	Description of code of ethics governing interactions with health care professionals	Discussion & Analysis	n/a	HC-BP-510a.2	<p>Catalyst employees are required to act with integrity and observe the highest ethical standards of business conduct in their dealings with Catalyst's patients, physicians, customers, and any additional stakeholders with whom they interact when performing their jobs. To this end, our Code of Business Conduct and Ethics includes provisions setting high standards specific to interactions with physicians and patients, professional conduct, and representation of clinical trial data, in addition to steps to take to avoid any potential misrepresentations of facts. We also provide training for our employees on expectations that must be met during interactions with health care professionals. Further, we have adopted the PhRMA Code on Interactions with Health Care Professionals to reinforce our intention that our interactions with health care professionals are professional exchanges designed to benefit patients and to enhance the practice of medicine.</p> <p>Through Catalyst's compliance program, operated by the Chief Compliance Officer, relevant training is provided to all employees based on roles and responsibilities. The Chief Compliance Officer is also head of the Legal, Medical, and Regulatory Review Committee that reviews and approves all relevant material to be used in the field to be sure that it is all on-label, well substantiated, and in compliance with all regulatory requires prior to filing any necessary materials with the FDA.</p> <p>In addition, our Compliance function conducts monitoring of field activities both in-person and through recorded reviews to ensure compliance with the Code of Business Conduct and Ethics. In the event a potential violation is detected, an investigation would be launched to determine if any violations occurred. In the case of violations, Catalyst would institute corrective and/or disciplinary actions.</p> <p><i>For additional information:</i></p> <p><a href="#">Code of Business Conduct and Ethics</a></p> <p><a href="#">PhRMA Code</a></p>

## Activity Metrics

Activity Metric	Category	Unit of Measure	SASB Code	Disclosure
SASB Healthcare: Biotechnology Pharmaceuticals (HC:BP)				
Number of Patients Treated	Quantitative	Number	HC-BP-000.A	For the full year 2021, less than 1,000 patients were dispensed FIRDAPSE® including patients receiving investigational and commercial product.
Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)	Quantitative	Number	HC-BP-000.B	<p>At this time, Catalyst has one drug, FIRDAPSE®, in our portfolio for both commercial and development purposes, though Catalyst is focused on evaluating potential transactions to add to this.</p> <p><i>For additional information:</i></p> <p><a href="#">Pipeline Webpage</a></p> <p><a href="#">MuSK-MG Clinical Background Webpage (Amifampridine)</a></p>