

## **THE COMPANY AND ITS BUSINESS**

### **Evolution of the Company and Definition of Terms**

I-PASS Patient Safety Institute, Inc. (referred to herein as “I-PASS Institute”, the “Company”, “us” or “we”) was founded in April 2016. We were founded to commercialize and expand the use of the I-PASS Program, which was developed through several studies of “I-PASS” (also referred to herein as the “I-PASS Program”).

The I-PASS Program was conceived by and developed by the “I-PASS Study Group”, a group of clinicians who ultimately became the founders of the I-PASS Patient Safety Institute. The I-PASS Study Group, which is led by our six founders, includes over 150 total medical professionals, and was started in 2008 when an initial single site pilot study was conducted at Boston Children’s Hospital. The I-PASS Study Group still exists today, and conducts continuing research associated with the I-PASS Program. Five of the six founders of the I-PASS Study Group are actively involved with the I-PASS Institute, including four of those five persons being members of the Board of Directors. The I-PASS Study Group does not offer commercial solutions that compete with the I-PASS Institute. In this business plan we will always refer to the I-PASS Study Group in those words.

The studies of the I-PASS Program (the “I-PASS studies”) have been structured and executed in order to provide statistically valid, evidence based results.

### **I-PASS is Recognized in the Medical Community and is Award Winning**

The I-PASS Program, and the work of the I-PASS Study Group, have been extensively published, and recognized through various awards, including:

- Published in over 20 articles in recognized medical journals and publications, including the New England Journal of Medicine, the Journal of the American Medical Association, British Medical Journal Quality & Safety, and Academic Medicine.
- In April 2017, the I-PASS Study Group received the prestigious John M. Eisenberg Award for Innovation in Patient Safety and Quality at the National Level. The Eisenberg Award is presented annually by the National Quality Forum and the Joint Commission.

### **The Company's business**

I-PASS Institute provides hospitals with implementation tools in the form of several software as a service (SaaS) solutions, and customized training and expert consultation to facilitate adoption of I-PASS, and ensure long-term sustainment. With our program, hospitals can implement I-PASS using a fraction of the time and resources they would spend doing it themselves. I-PASS Institute has an exclusive license, from Boston Children’s Hospital, to use I-PASS for handoffs (see “Intellectual Property” below).

I-PASS is a package of interventions that has been created over the years from the various studies, building on the original I-PASS mnemonic (a pattern of letters acting as a memory aide) and a series of complementary interventions designed to improve patterns of

hospital communication. See the “Products and Services” section that follows for a detailed discussion of our I-PASS SaaS and service offerings. To drive significant changes in patient safety, I-PASS needs to be systematically adopted and used daily by health care professionals in their written and oral communications.

We work with hospitals to create a customized program to ensure adoption and long-term sustainment of I-PASS. I-PASS can be implemented in individual departments, but for the greatest benefit, it should be adopted throughout an entire institution. We work with institutions to develop an implementation plan that best meets the hospital’s / department’s goals.

The I-PASS Study Group has been driven to further disseminate I-PASS in order to promote patient safety. In 2015, the I-PASS Study Group entered the Harvard Business School / Harvard Medical School Health Acceleration Challenge, a “scale up” competition that focuses on compelling, already-implemented health care solutions and helps them to grow and increase their impact through powerful networking and funding opportunities. There were 478 applicants, and I-PASS Study Group was selected as one of four finalists. As a finalist, the I-PASS Study Group received invaluable guidance from the Harvard Business School / Harvard Medical School sponsors, including a recommendation to start a company in order to disseminate I-PASS more broadly. Following that recommendation, the founders recruited the current management team, and the I-PASS Patient Safety Institute, Inc. was founded in April 2016.

Since its inception, we have invested in the development of our SaaS product offerings and enhancing related training programs and methodologies that allow for I-PASS to be adopted more easily by hospitals. We also have invested in building our sales, marketing and project management / execution capabilities to allow us to serve more institutions. In December 2016, we entered into an exclusive trademark license with Boston Children’s Hospital for the use of I-PASS in connection with handoffs in a clinical setting. See the Intellectual Property section below for further discussion.

The I-PASS Patient Safety Institute, Inc. currently has 3 full time employees, and 1 contract employee who devotes approximately three-quarters of his time to the business. Additionally, five of our six founders are actively involved with the Company, and each devotes approximately 20% of their time to the business, supporting the continued development of our product and service offerings, participating in customer deployments of our software and services, and supporting sales and marketing efforts.

## **Background: Communication Failure & Patient Handoffs**

I-PASS is an evidence-based package of interventions created to reduce communication failures during patient handoffs. A patient handoff occurs each time there is a shift change between medical professionals, as well as when a patient is transferred from one department in a hospital to another department. An average sized hospital, based on an estimated 2 to 3 handoffs per patient, per day, will have approximately 1.6 million handoffs per year. Historically, the process for conducting high quality handoffs within health care settings has not been formally taught to doctors or nurses; they are non-standardized, and vary both within an institution and between institutions. Each handoff represents a critical moment in patient care. When an incomplete or incorrect handoff is conducted, a medical error may arise.

According to a study published by the British Medical Journal in 2016, medical errors are the third leading cause of death in the United States, causing 251,000 deaths in 2013 alone. According to the Joint Commission, an organization responsible for the accreditation of hospitals in the United States, miscommunication has consistently been identified as one of the most important root causes of medical errors. Data reported to the Joint Commission in 2016 showed that communication errors among staff was the most frequently identified contributing factor to sentinel events, the most serious of medical errors.

Medical errors are expensive, and add significant costs into the U.S. healthcare system. In a 2015 study by CRICO, an insurance program serving the Harvard Medical Community that provides medical insurance products and patient safety resources to its members, it was determined that communication was a factor in 30% of malpractice cases studied from 2009 to 2013. Those 7,149 cases that included communication errors as a contributing factor incurred \$1.7 billion in losses, nearly \$250,000 per case. Additionally, provider to provider communication errors are more likely than the average of communication failures studied to result in a loss, and for an amount that is larger than the average.

In a more recent May 2017 presentation at the Pediatric Academic Societies (PAS) Meeting, data was presented regarding a random sampling of 23,000 malpractice claims from 2001 to 2011. In that analysis, it was noted that 52.0% of malpractice claims involved a communication error. In 41.4% of those cases a handover of care was involved. The researchers noted that it was possible that a handoff process and tool may have averted 83.6% of the claims. The aggregation of that data indicates that 18.0% of all malpractice cases could be averted with the use of a handoff tool, such as I-PASS. A 2010 study indicated that 2.4% of all annual healthcare spending in the United States, which equals \$55.6 billion (approximately \$70.8 billion in 2016 after accounting for inflation) is spent on medical liability issues. Those issues include downstream medical procedures as well as malpractice claims and related costs. Extrapolating the 18.0% against that figure results in an annual \$12.7 billion potential in healthcare spending each year.

The I-PASS Study Group's initial single site pilot study was conducted at Boston Children's Hospital, and funded by CRICO. CRICO is an insurance program serving the Harvard Medical Community that provides medical insurance products and patient safety resources to its members. Several additional I-PASS studies have been conducted, and are still in progress, following that initial study. Those additional studies have involved over 50 leading hospitals in the U.S. and Canada, and included the support of the Society of Hospital Medicine, which is a professional medical society dedicated to providing exceptional care to the hospitalized patient. The total funding in these studies exceeds \$7 million, and the funding for those additional studies came from several sources including federal grants from the Department of Health and Social Services (DHSS) and the Agency for Healthcare Research

and Quality (AHRQ), the Patient-Centered Outcomes Research Institute (PCORI), and additional funding from CRICO.

In a large multicenter trial, implementation of I-PASS was associated with a 30 percent reduction in medical errors that harm patients (New England Journal of Medicine 2014). A successful implementation of I-PASS requires detailed milestone planning, effective staff training and robust measurement to achieve consistent and sustained changes in oral and written communication processes. I-PASS is now being successfully used, either partially or fully, by more than 50 leading hospitals in the U.S.

The successful use of I-PASS by medical professionals benefits all involved parties. Most importantly, the safety and health of the patient is improved. Additionally, medical professionals, hospitals and medical insurers benefit from avoidance of the social, psychological, and financial burdens of making errors that harm patients, as well as by enhanced reputations. The reduction of medical errors eliminates costs from the healthcare systems through both the elimination of events caused by the errors, and also through the reduction in associated malpractice claims that may derive from such a medical error.

### **The Market/Initial Sales**

We believe that there are a number of market forces and operating requirements that will continue to push hospitals to adopt I-PASS. Every hospital has a need to continually train their staff, whether that is due to the growth of the hospital, churn of its existing staff, or the annual class of new residents. We believe that many hospitals see, or will see, our I-PASS offerings as a way to leverage their stretched internal resources to train their staff.

Additionally, there are external factors that we believe will continue to drive hospitals to adopt improved communications such as I-PASS. For example, U.S.-based teaching hospitals, medical centers and health systems that are affiliated with the Accreditation Council for Graduate Medical Education (ACGME) undergo safety visits every two to three years called Clinical Learning Environment Reviews (CLER). Those CLER reviews have six focus areas: patient safety; health care quality; care transitions; supervision; clinical experience and education and fatigue management and mitigation; and professionalism. In March 2017, the ACGME released its National Report of Findings 2016, Issue Brief No. 5, Care Transitions. In that report, it was noted that most of the observed institutions did not appear to have a standardized approach to facilitating resident and fellow hand-offs at change-of-duty, and that a limited number of those programs appeared to use formal criteria to assess residents' and fellows' skill in change-of-duty hand-offs. Our product and service offerings were designed to meet those needs.

We also believe that hospital insurers will continue to see the benefits of the adoption of I-PASS and support its further implementations. As noted above, CRICO was an early supporter of I-PASS clinical efforts, and in its 2015 Annual Benchmarking Report they documented the high costs of communication failures in the healthcare system. We believe that a broadened recognition of these costs will expand the push by insurers to have hospitals adopt a standard of communication for patient handoffs.

We are initially pursuing the U.S. hospital market. Within that market, our larger opportunities are directed at large academic medical centers, and our offerings are applicable to nearly all hospitals with inpatient services. We estimate this U.S. market for our products and services to be in excess of \$500 million per year.

The initial studies of I-PASS related to communication between healthcare professionals, and those studies have been primarily in the U.S. Notwithstanding the location of the I-PASS studies, the use and value of I-PASS is equally valid worldwide, and we plan to pursue markets outside of the U.S. We estimate that the market outside of the U.S. is equal to or greater than the size of the U.S. market.

In addition to I-PASS being used for communication among medical professionals, the I-PASS Study Group is currently broadening I-PASS studies for use in the communication between: (i) medical professionals and the patient / the patient's family (Patient and Family I-PASS), and (ii) the use of I-PASS in an outpatient setting (Ambulatory I-PASS). Pending the results of those studies, we believe that these may be incremental markets for us in the future.

## **Intellectual Property**

We have entered into an exclusive trademark license agreement with Boston Children's Hospital in December 2016 for the use of the I-PASS trademark in connection with handoffs in a clinical setting. The Company has the exclusive right to use the trademark for an initial period of 48 months. The trademark's "Territory" is for the United States, excluding one branch of the U.S. government, and may be used outside of the United States with approval by Boston Children's Hospital. If the eligible sales, as defined in the license agreement, exceed \$2,000,000 in the initial 48-month period; the term is automatically extended for an additional 48-month period. If the eligible sales exceed \$2,000,000 in the additional 48-month period, the exclusive trademark license will be extended until such time as the license agreement is terminated or the license becomes non-exclusive as provided in the license agreement. If at the end of the initial 48-month period or at the end of the second 48-month period eligible sales are less than \$2,000,000, the trademark license shall automatically revert to a non-exclusive license, and may continue in full force and effect until such time as the license agreement is terminated by either party as provided in the license agreement. Termination by Boston Children's Hospital is allowable in defined cases of non-performance by the Company, or bankruptcy or dissolution of the Company.

## **Products and Services**

The I-PASS Institute has developed several proprietary SaaS product offerings to allow hospitals to implement I-PASS more effectively than they could on their own. Our SaaS product offerings are sold on a subscription basis, based on the size of our customer, as measured by a number of factors, including the number of medical professionals being trained, and the size of the hospital or department being implemented. Our product and service offerings are most effective when purchased and implemented collectively by our customers, but we may from time to time sell a customer a subset of our products or services.

Our current SaaS offerings, I-PASS Virtual Immersive Learning and I-PASS Observation & Measurement do not collect any confidential patient information, and do not require any integration to a hospital's existing electronic health records systems.

### **I-PASS Virtual Immersive Learning**

I-PASS Virtual Immersive Learning (also referred to as I-PASS Learning) is a training platform that is accessed over the internet. I-PASS Learning provides an interactive experience in which the person being trained is taken through a curriculum, and is then required to provide an actual handoff and grade themselves against required components of the I-PASS mnemonic. I-PASS Learning consists of modules that are tailored to the specialty of the learner, and we intend to add additional specialties in the future.

I-PASS Learning allows training to be conducted from any location with an internet connection and personal computer. The training can be taken at a time that works within each individual medical provider's schedule. Prior to the development of this product, medical professionals have generally been trained in small groups, requiring adjustments of normal schedules of the medical staff around defined training times, and requiring significant investment of time by hospital management and administrators.

### **I-PASS Observation & Measurement**

I-PASS Observation & Measurement is a web-based tool that is used on the hospital floor. This product is used by one person who observes actual handoffs conducted between medical professionals. Hospitals do not measure every handoff, but rather a sampling of handoffs. Each observed handoff is graded for adherence to the elements of the I-PASS standard and the quality of information exchange, thus allowing the hospital to assess the quality of each handoff, and to measure the collective use of I-PASS by its staff over time. In addition, these observations are meant to provide feedback to the learner to promote effective use of the technique.

The I-PASS studies have found that observation and measurement of handoffs is a critical element to achieving improved patient safety results. I-PASS Observation & Measurement is used to provide not only the specifics on a handoff, but also has been built to allow for comparisons of departments or units within a hospital, the totality of the hospital, and comparisons of performance of one hospital with another. When comparing a department or hospital to another hospital, the comparative data are aggregated and deidentified. Access to this information is valuable to the hospital administration team, allowing it to evaluate its staff relative to this important safety patient initiative.

### **I-PASS Professional Services**

Our professional services offering include expert consulting provided by our founders and other members of the I-PASS Study Group. Those persons are independent contractors to us. Through their work on the various I-PASS studies, this group of medical professionals (also referred to as "Mentors") has gained expertise in how to implement I-PASS in a hospital, including all facets of the implementation, from training to the more complicated aspects of garnering institutional support and enabling cultural changes. Through that expertise and leveraging the SaaS products we have developed, we can help hospital implement I-PASS much more efficiently than they could on their own.

We also provide other professional services associated with the setup and implementation of our products within a hospital.

### **I-PASS Written Templates & Integration into Electronic Health Records**

An important part of the communication between medical professionals is the written portion of a handoff. Leading electronic health record (EHR) systems such as Epic and Cerner contain limited I-PASS templates as a part of the EHR. These templates are a good start in collecting data and using those data in a handoff, but each hospital and often each department within any given hospital have their own workflow that requires the I-PASS template to be configured to their needs.

Our experience allows us to assist hospitals with their needs in a number of ways. First, our medical professionals are able to leverage their experience to provide professional services to a hospital to allow blueprints and existing templates to allow a hospital's information technology staff to configure enhanced I-PASS templates. We also partner with other third party providers who have applications that address written handoffs, these third-party solutions may or may not integrate to a hospital's EHR, again depending on the preference of each hospital.

### **Competition**

The I-PASS studies have been structured and executed in order to provide statistically valid, evidence-based results. I-PASS is the only program that we are aware of that offers such results. We have built the I-PASS Institute's product and service offerings based on these findings, and we are not aware of any other communication standards that measure up to such rigor.

Hospitals may elect to try to implement the I-PASS program on their own, using their own staff and other resources to do so. A recent publication documenting the implementation of I-PASS at a large academic medical center noted that the adoption required major cultural change. Additionally, the article noted that assuring consistent and sustained adoption across all services is more challenging, requiring adaptation of the basic I-PASS structure to individual hospital needs and workflows.