Proposal **2**

1. Goals and Objectives **2**

2. Technical Approach **2**

A: Current Assessment of Need *2*

B: Intervention Design and Methods *4*

Localization of Educational Materials and Resources 4

Counselors Education 4

Program Implementation/Service Delivery 6

C: Evaluation Design *6*

3. Detailed Workplan **7**

D: Organizational Detail **8**

Proposal

1. Goals and Objectives

The overall goal of this new initiative is to take the resources and expertise of the CS2day Partners and apply them in China. This effort will put the knowledge, skills and resources developed in the original CS2day initiatives to good use in a place where they are needed the most. We will adapt, test and transfer culturally appropriate education and intervention activities to mental and behavioral health professionals in China. More specifically, we will educate a group of Chinese counselors to develop the skills needed to effectively provide their clients with smoking cessation assistance thereby reducing the smoking rate. These counselors will not only translate the knowledge and skills into clinical practice to help their clients quit smoking, but will also become the seeds for disseminating the skills and resources among Chinese mental and behavioral health professionals. Throughout the implementation of the new initiative in China, we will systematically evaluate the effectiveness of the adapted messages, tools and resources and the outcomes of clinician education in terms of changes in knowledge, skills and effectiveness in delivering cessation assistance to smokers, as measured by quit rates.

Our objectives for the CS2day initiative in China are four-fold. (1) We will complete the translation and localization of the CS2day tools and resources for use by Chinese clinicians and other mental health professionals. (2) We will educate a group of 20 mental health professionals on the adapted curriculum. (3) These professionals will then implement the adapted program by providing smoking cessation assistance to their clients. (4) Throughout the process of program adaptation, clinician-education and field implementation, we will systematically and rigorously evaluate the effectiveness of the program in the Chinese context.

This project will provide the opportunity to adapt, test and evaluate smoking cessation education through an employer-based community in China. Future opportunities for expansion will be explored based on the results of this pilot.

2. Technical Approach

A: Current Assessment of Need

The hazards of tobacco consumption in general and cigarette smoking in particular have long been a global epidemic. According to data from the World Health Organization (WHO), although the smoking rates in developed countries such as the United States have been declining due to increased public awareness and effective intervention programs, the same encouraging trend has not been observed in many developing countries such as China. In developing countries, the health problems caused by smoking place even a greater strain on

the healthcare systems, which are often inadequate and fragile in the first place. WHO has identified smoking as one of the most life threatening health problems, and reduction and/or cessation of tobacco consumption has a very high reward in health improvement and future health cost reduction. The need for smoking reduction and cessation is more urgent in developing countries like China than anywhere in the world. China is the world's largest manufacturer of cigarettes and home to the world's largest population of smokers. According to the WHO's Global Adult Tobacco Survey, the country has 301 million smokers. More than half (52.9%) of Chinese males and 2.4% of females, 15-years-old and above, smoke. Among the country's current smokers, 85.6% smoke every day. The current trend in the country's effort to control and reduce smoking is not optimistic; there was almost no reduction in the male smoking rate from 2002 to 2010, and the smoking rate among young women had actually increased.

Introducing education and intervention programs that have been proven effective in the United States to developing countries with appropriate cultural adaptation will help reduce the gap in smoking cessation. This effort will improve access to smoking cessation assistance in China, a key location in combating the global epidemic of tobacco consumption.

Our choice of China as the next focus of CS2day's international expansion is based on three main opportunities, (1) the country's large number of current smokers, (2) inadequate dissemination of information about the harm of tobacco use and benefits of cessation and, (3) lack of systematic, evidence-based assistance programs in the country's healthcare communities to help smokers quit.

Lack of information and education is part to blame for the grim situation in the smoking epidemic in China. Many people in the country are unaware of or are unclear about the impact of smoking on their health. According to WHO's 2010 survey, more than three quarters of Chinese respondents lacked adequate knowledge about the harm of first-hand smoking. About two-thirds of Chinese respondents lacked accurate information about the effects of second-hand smoking. A total of 86% of respondents did not realize that the claim "low tar equals low harm" was invalid. To make the situation worse, 54.7% of doctors did not know that the "low tar, low harm" claim was false. Prevalence of misleading information and lack of awareness of the harm of smoking in the population restricts smokers' motivation to quit.

Awareness of the harm of smoking is inadequate even among health care providers, hindering their ability to play an active and effective role in smoking cessation. Among current smokers who visited physicians within the last 12 months, only 40.8% were asked about tobacco use and only 33.9% were advised to quit by their doctors (WHO, 2010). In other words, about 60% of smokers were not even asked about their tobacco use when they visited their doctors. The educational component of this initiative will play a significant role in filling the

clinicians' gaps in the knowledge and awareness of the health implications of smoking in various segments of the Chinese society.

Smoking is a stubborn addiction; it takes more than will-power to quit. Effective assistance from medical personnel and other healthcare providers is necessary but grossly lacking in China. According to WHO's 2010 survey, 36.4% of Chinese smokers had attempted to quit within the last 12 months; however, 91.8% of them had received no smoking cessation assistance. Left to combat the smoking addiction on their own, a large percentage (33.1%) of those who had tried to quit, resumed smoking. Given the serious situation of tobacco use and lack of effective assistance programs to help people quit, this initiative is greatly needed in China. Introducing and implementing this program in China will contribute toward the goal of our original CS2day initiative of increasing smoking quit rates by assisting clinicians through education on evidenced-based smoking cessation strategies.

B: Intervention Design and Methods

The CS2day China project consists of four major components, i.e. localization of the materials and resources, counselor education, service delivery and program evaluation. We will describe the first three components, explaining the key activities, expected outcomes and methods of evaluation. Program evaluation is embedded in all of the components.

Localization of Educational Materials and Resources

The original CS2day initiative developed an extensive list of educational materials and resources for clinicians to help smokers quit. These materials will be adapted for the Chinese health care providers. Considerations will be given to cultural norms, needs and life-styles of Chinese clients as well as the competence and knowledge of local counselors. Medication and counseling recommendations will be customized based on local availability. This work will be undertaken by a team of professionals from both the US and China. The US team will consist of experts from the CS2day partners with in-depth knowledge and expertise in the contents of the program. The Chinese team will consist of mental health professionals who are Chinese-English bilingual. The teams will evaluate the cultural appropriateness, applicability and practicality of the entire tool kit to decide which part will be directly translated and which will be modified. The translation and adaptation will be completed collaboratively by the teams.

Expected outcomes include the development of culturally appropriate cessation tools and resources. The evaluation of this component will be based on the completeness, quality and usability of the localized materials. These materials will also be placed on the CS2day website and be publicly available for use worldwide.

Counselors Education

The CS2day China initiative will provide 20 Psychcn-Chestnut Global Partners (PCGP) with three continuous months of education including a four-week intensive educational experience followed by monthly webinars with the goal of improving cessation efforts using resources from the CS2day project. The education will be a collaborative- interactive experience using best practices in adult education. These best practices will be modeled through the experience and all materials will be available to the learners for use in future educational opportunities.

The activities will employ both face-to-face and Web-based meetings, supported by conference calls. Experts in the CS2day program from the United States will serve as the faculty. The first phase of the program will consist of three days of face-to-face instruction including lecture, case-based small group discussions and interactive skill building workshops. The meeting will take place in Beijing, where most of the PCGP counselors are located, with the US and China experts providing instruction on-site. The next three weeks will rely on web-based meetings and conference calls for the consolidation of the knowledge and skills. The learners will be broken into two groups to optimize interaction, with each group participating in weekly calls. Two additional calls will occur in the successive months as follow-up to the intensive experience. Each participant will share experiences through this collaborative education with other learners to ensure all benefit from experiences to develop best practices. Barriers to implementation will be identified and discussed.

Assessment will be continuous with each meeting and action. All educational activities will be measured for level of satisfaction, learning and competence through pre and post-activity assessments. Clinical vignettes with multiple choice questions will be used to assess clinician competence and decision-making. Learning and the application of knowledge are expected to increase by more than 50% with this education.

Counselor performance will be examined using two methods, simulated patients and practice assessment surveys. For the simulated patients, a baseline will be obtained using a sample of 5 counselors by calling and requesting assistance with smoking cessation. A rubric with best practices will be used to score the counselors both prior to and after the educational interventions. Additionally, all twenty counselors will complete a practice assessment survey allowing the clinicians to report current practices. This will be compared to the simulated patient experience for consistency. The simulated patient will be used post-activity with all 20 counselors to provide feedback and allow comparison to pre-activity assessment of practices. We expect dramatic changes in clinical practice as currently little is done on smoking cessation.

Pre-Program	**Examining**	**Data**
5 Patient simulated interviews	Current practices	Observation
20 Practice assessments	Current practices	Self-report
Post-Program		
20 Patient simulated interviews	Current practices	Observation

20 Practice assessments	Current practices	Self-report

Program Implementation/Service Delivery

To assist with application of the knowledge and skills obtained through the education and assess the effectiveness of this program, the counselors will provide assistance to smokers and assess quit rates. PCGP will promote the CS2day program to client companies to launch a new smoking cessation service. PCGP account managers and counselors will provide information about the CS2day service in routine Employee Assistance Program (EAP) promotion materials and will circulate information among employees of the selected client companies. These activities will increase the awareness among potential clients and motivate them to seek help in smoking cessation. The information will also include detailed direction on how to use the well-established and familiar 24/7 EAP hotline to access cessation assistance. We anticipate collecting data for a minimum of 150 cases in this treatment group.

Clients interested in CS2day services will call the 24/7 hotline operated by PCGP call center. The intake counselor will complete the baseline assessment and provide smoking cessation assistance. The intervention will follow best practices established in the US Public Health Service Guideline *Clinical Practice Guideline: Treating Tobacco Use and Dependence 2008 Update,* as closely as possible. Post-intervention assessment will be completed 90 days after the conclusion of the intervention to assess sustained impact.

The patient assessment instrument will include items adapted from the Fagerstrom Nicotine Reliance Rating, an instrument well-accepted and widely used in smoking research in China. The instrument will gather information on smoking status to allow calculation of quit rates along with frequency and routines to quantify smoking behavior and calculate an index for the level of reliance. We will report quit rates as the percentage of clients who became and remained abstinent during the treatment and 90-day follow-up period. We will also report changes in the level of reliance.

C: Evaluation Design

The assessment methodology for each individual component was described above. Analysis and reporting will occur as the component is completed. However, the overall assessment and success of the project will be reported upon conclusion of the project in December 2014 and will include each individual component.

Assessment Methodology for Smoking Cessation Interventions

This study uses a quasi-experimental design to test the effectiveness and value of an education-based smoking cessation model. Ideally, the study would use either a "no treatment" control or a comparison modality as a method of providing strong internal validity in the assertion of causal direction. Unfortunately, as is the case in most practical tests of behavioral health intervention, it is unethical to withhold treatment from employees wanting to quit

smoking. There is a lack of comparable modalities that can be reasonably compared to the experimental treatment. Given that the project is primarily interested in assessing the effectiveness in transferring the US based intervention to China, the formal and informal evaluation of the program will focus largely on the issues of change from baseline, and the qualitative experience of the subjects for the current project. Therefore the statistical analysis will focus on the matter of change in smoking behavior, while the qualitative aspects will focus on the entire experience of the subjects in terms of the educational process and the manner in which it brought about the change in smoking behavior. This will leave the concern of internal validity with a formal comparison control for a later study.

Quantitative Analysis. The data for this study have a hierarchical structure, meaning that observations (pre/post) are nested within participant, and participants are nested within counselor. The clustering of data may violate the assumption of independence of error terms, which could result in reduced error terms and increase the likelihood of a Type I error. To control for this violation of assumptions, all analyses will be conducted using HLM to accommodate multi-level data. The dependent measure will be smoking behavior. A short client survey with satisfaction and counselor performance metrics will be used post intervention.

Qualitative Analysis. Structured intervention of the small sample from the study will be used to assess the quality of the program and effectiveness of the educational approach. Subjects will be asked about the process by which the specific educational components impacted their smoking behavior.

Protection of Human Subjects. The project will use Chestnut Health System's NIH certified Internal Review Board for the protection of human subjects to provide protection for the human subjects in the study.

Dissemination of Results. As mentioned all resources will be available on the CS2day website. The description and/or results of our work will be submitted for publication in a scientific, peer-reviewed journal such as the Journal of Health Promotion as well as an appropriate Chinese outlet to encourage dissemination in China.

3. Detailed Workplan

The initiative will begin immediately upon award of the grant. CS2day faculty will work with the PCGP team lead to examine resources and materials to be translated and adapted to meet cultural needs. Development of the practice assessment and framework for the simulated patient interviews also begin for collection of pre-activity baselines. The five baseline interviews will be conducted in mid-January 2014 and the practice assessment completed in the same timeframe to provide information for the planning of the live meeting. Logistics will be coordinated for a live meeting in Beijing during March. Follow-up

webinars will be conducted with a translational tool used to facilitate the exchanges with expert participation from both countries. Evaluation will occur with each activity and a more formal assessment will be completed at the end of the project with patient simulated interviews occurring in October. Post-activity practice assessments will be distributed on afterwards and data collected through November. The final report will be completed by December 19, 2014.

Milestones	Timeline	
LOA completed	12-15-13	
Live education sessions	3-28-14	
Follow-up webinars	5-14-14	
Outcomes reporting and reconciliation	12-19-14	

Timeline:

Key Events	Completion Date	Responsible Partners
Project planning and finalization	1-10-14	All
Assessment tool development	2-13-14	CS2day, CGP
Educational planning and tool adaptation	2-14-14	US faculty, PCGP
Pre-activity practice assessment and simulated patient interviews	2-7-14	CS2day, PCGP
Analysis and reflection	3-14-14	All
Live education	3-28-14	US faculty, PCGP
Reporting and reflection	4-4-14	All
Follow-up webinars	3 in April, 1 in May, 1 in June	US faculty, PCGP
Final evaluations, practice assessment, simulated patient interviews and patient data collection	10-31-14	All
Analysis	11-28-14	All
Report	12-19-14	All

D: Organizational Detail

Cease Smoking Today (CS2day) is a multi-organizational education initiative designed to provide physicians and healthcare professionals with effective and clinically relevant strategies targeted to increase the smoking quit rates for patients followed in multiple practice settings. The CS2day project began in the United States in 2007 to disseminate information from the Public Health Service *Clinical Practice Guideline: Treating Tobacco Use and Dependence 2008*

Update. The initial educational effort reached more than 43,000 clinicians from all 50 states and 10 foreign countries via certified education and derivative resources consisting of more than 130 live activities, four comprehensive performance improvement projects, 15 enduring activities, three educational exhibits, and a toolkit comprised of 83 educational resources. Outcomes demonstrated changes in knowledge, behavior, and patient health proving that multifaceted education can impact public health.

In year 2 of our work on smoking cessation, CS2day extended the innovative approach by reaching out to community-based partners with the “Building on Success” grant. By working hand-in-hand with organizations and communities that were invested in increasing tobacco cessation rates, the CS2day collaborative was able to leverage education effectively in projects across the country. The BOS Communities reached more than 2,800 clinicians through the 121 certified educational activities. More than 2,300 clinicians received continuing education credit from the six types offered. Learners included physicians, pharmacists, nurse practitioners, public health nurses, physician assistants, and other healthcare providers. Moreover, these communities made contact with more than one million stakeholders through a variety of innovative methods. Chestnut Global Partners along with Aetna partnered with us on one of the original smoking cessation communities. Many of the BOS Communities continue the important work in smoking cessation today.

Chestnut Global Partners (CGP) has been providing Employee Assistance Programs (EAP) and related workplace wellness services since 1984. In 2000, CGP developed capabilities outside the U.S., beginning in Brazil and now has native/host country EAPs and international networks covering over 125 countries, as well as equity-interest joint ventures in Brazil, China, Mexico, Russia, India and Native America. CGP directly provides global EAP services to 174 western multi-national employer clients although each of our Joint Ventures has their own book of indigenous, in-country based employer business. Our capabilities have allowed us to provide services in a range of locations, whether they are large urban settings or remote locations such as the deserts of Mongolia, the Ural Mountains of Russia, or the world’s largest cities such as Beijing, Sao Paulo, or Mexico City. Some of our multi-national customers include Caterpillar, ConocoPhillips, Chevron, Archer Daniels Midland, and the Habitat for Humanity, to name a few.

Chestnut Global Partners, LLC (“CGP”) is an Illinois limited liability corporation formed on April 15, 2005. The sole member and parent corporation of CGP is Chestnut Health Systems, Inc. (“Chestnut”), an Illinois not-for-profit corporation incorporated on July 28, 1970 and exempt from federal income taxation under Section 501(c)(3) of the Internal Revenue Code. Russ Hagen serves as the Chief Executive Officer of both Chestnut and CGP.

It is an important distinction that CGP is an independent company and international EAP is our focus and specialty. We are not owned by a large insurance company where international EAP is part of a long list of products. We are also the behind

the scenes International EAP partner for numerous other EAPs (including our competitors), as most do not have the breadth and depth of resources and on the ground services that would allow them deliver a global EAP offering.

The specific clinical team in China is Psychcn-Chestnut Global Partners (PCGP), an established and leading EAP provider in China. PCGP employs 30 full-time, in-house counselors and 116 affiliate counselors located in 36 cities throughout China. These professionals provide mental and behavioral health counseling and workshop facilitation for client employees. They are licensed to provide psychological counseling in China and their amount of experiences exceeds the local standard. They also receive professional supervision, including regular supervision from Chestnut Global Partners' US team. With promotion of health and well-being as a major component of their professional activities, the PCGP counselors are in a good position to engage tobacco users in a cessation program.

PCGP's Clients include large Chinese and multinational companies, serving approximately 180,000 employees throughout China. This large pool of clients will provide the participants to the CS2day program. Many of PCGP's clients have a keen interest in improving workplace heath, thus will grant PCGP considerable assistance in promoting smoking cessation services among their employees.

The CS2day China initiative is unique in that it will leverage the infrastructures and resources of an established Employee Assistance Program (EAP) in China as a launch pad and platform of implementation. As a result of rapid economic growth and integration with the global economy, more and more Chinese companies are starting to provide EAP services as a prepaid benefit to help employees and their families with a variety of personal concerns that may have negative effects on job performance. A large proportion of employees' personal and family issues that EAPs deal with are related to mental and behavioral health. EAP offers a useful platform for launching various health improvement services. Smoking cessation programs can be seamless placed under the EAP umbrella. The following summarizes the strengths of EAPs in implementing the smoking cessation program in China, especially in clinician education and service delivery.

First, EAPs employ on-staff and affiliate mental health counselors; these professionals will be educated on best practices to work with clients on smoking cessation. These counselors' affiliation with an established EAP ensures their competence in providing mental and behavioral health guidance have been properly evaluated, and that they receive continuous professional supervision. Meanwhile, the EAPs may also offer effective systems and resources for organizing counselor educational activities.

Second, EAPs will provide large and stable pools of clients/patients for the smoking cessation program. A major barrier for people to access mental and behavioral services in China is the cost, which is high compared with people's average income and usually not covered in the medical insurance plans. Services through EAPs are low cost to the employees, as the costs are covered by the employers. This arrangement greatly reduces the financial barrier for those covered in the EAP plans to use mental health services including smoking cessation assistance.

Third, the EAP infrastructures offer employees an easy access to mental health services, including smoking cessation assistance. Most EAPs operate call centers that offer 24-hour, seven-days-a-week hotlines for their clients' employees. These hotlines provide evaluation, counseling and scheduling of further assistance. Employees seeking smoking cessation assistance can use the same hotlines as their point of contact with smoking cessation counselors. Measurement and evaluation of the program's effectiveness can also be implemented through the call centers.

Staff Capacity.

The CS2day partners with specific roles in this project include the California Academy of Family Physicians, Interstate Postgraduate Medical Association, Healthcare Performance Consulting and CME Enterprise. All have extensive experience with project management and leadership both within their organizations and in smoking cessation.

PCGP will take the lead on translating the material and adapting the curriculum for the Chinese employees. PCGP will also arrange the educational venue, recruit participants and collect data for the outcomes assessment.