

## **Overall Goal and Objectives**

*EnGAging an Interdisciplinary Team for NSCLC Diagnosis, Personalized Assessment and Treatment (GAIN)* GAIN was an educational curriculum designed to improve the knowledge, competence, and performance of a team of interdisciplinary specialists responsible for assessing and managing patients with non-small cell lung cancer (NSCLC). The original GAIN project conducted in the U.S. in 2012, educated pulmonologists, pathologists, oncologists, thoracic surgeons, and other members of the NSCLC management team. Its primary goal was to identify the best methods to evaluate patients who are suspected to have NSCLC by defining the molecular biology of the tumor. The GAIN curriculum included a performance improvement module (PIM) for pulmonologists linked to the American College of Chest Physicians' (ACCP) AQUIRE data system, the American Society for Clinical Pathology's (ASCP) e-learning and CheckPath modules for pathologists, and 10 full-day Regional Summits. The Summits featured didactic lectures, breakout sessions that focused on small group interdisciplinary case-based education, hands-on simulation skills training in bronchoscopy, pathology-specific cases using images, and problem-based exercises. Much of the critical transfer of learning from GAIN occurred during the small group breakouts where participants engaged interactive learning methods (eg, hands-on simulation skills training, case- and problem-based exercises, and APP-based gaming). The integration of technology into the educational model engaged participants further into the learning process and improved impact.

Outcomes results from GAIN revealed that almost all (99%) participants improved their competence and they expected improvements in their performance which would lead to better patient outcomes. Self-reports concerning performance on the 13 steps of endobronchial ultrasound (EBUS), bronchoscopy technique, and pulmonary anatomy pre- and post-activity reflected an increase in participant confidence in all categories. A majority (87%) of learners said they planned to make changes to their practice as a result of the activity. These changes included ensuring that an adequate biopsy sample is obtained, and maintaining a high knowledge and competence level in the areas of biomarkers and targeted therapy. In a long-term survey conducted after the Regional Summits, participants reported that they increased their use of proper sampling techniques (27%), shared knowledge with colleagues (20%), increased dialogue with team members (19%), and sought more knowledge about sampling techniques (18%) or anatomy (10%); all to ensure adequate biopsy tissue acquisition and processing. With regard to the use of biomarkers, 21% of long-term survey respondents indicated they had increased their use of biomarker analysis and approximately 30% of respondents improved their communication with colleagues about biomarker site/sample size, handling, preparation, testing, and interpretation. Additionally, assessment data was collected from ASCP's CheckPath program to evaluate physician performance using a quasi-experimental research design. Based on this data, GAIN Summit participants scored an average of 89% on the CheckPath Assessments of NSCLC pathology performance while the control group scored an average of 82% on the assessments.<sup>1</sup>

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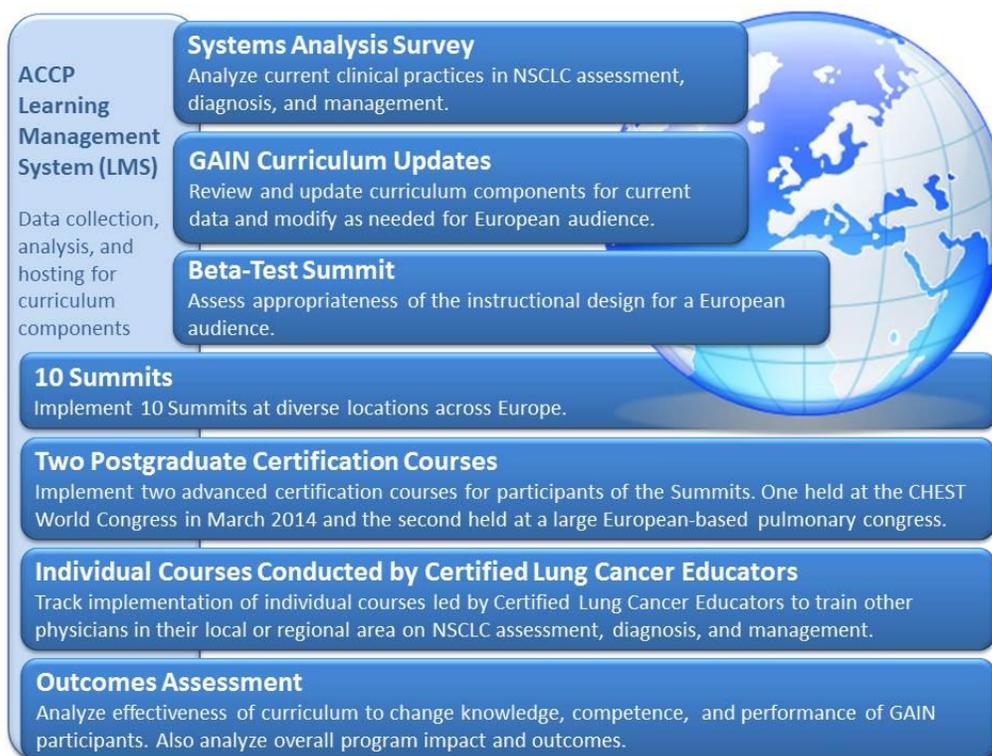
<sup>1</sup> ASCP. Data on file.

GAIN also revealed wide variability in practice across program locations and, in general, suboptimal practices among physicians across the patient care experience. These variances in practice included referral to differing specialists, knowledge, collection of adequate tissue specimens using current techniques (including bronchoscopy), and choices and performance of tissue sample assessment; all to provide information essential for proper treatment. Specifically, information acquired from the project regarding health systems barriers in the U.S. was used to create a second grant-funded project, titled *Engaging Multidisciplinary Teams to Improve Patient Outcomes With NSCLC using Educational Resources* (EMPOWER).

An extension to GAIN is proposed to expand this curriculum into Europe. Europe is the logical choice for expansion of the GAIN curriculum, because after North America, Europe has the highest incidence and mortality rates for lung cancer.<sup>2</sup> The following depicts the components of the GAIN Global Initiative.

## GAIN GLOBAL INITIATIVE

Use educational resources from U.S. GAIN curriculum that maximize cultural and focused training techniques of respirologists, pathologists, oncologists, thoracic surgeons, and other healthcare providers in Europe to optimize the transfer of learning to clinical practice for the identification and treatment of NSCLC.



Close partnering with European organizations and clinical leaders/champions is vital to conducting a successful program. European physicians expressed interest to ACCP and ASCP in implementing GAIN in their countries because there are currently no comparable programs. Specifically ACCP has communicated with a large European-based pulmonary organization and the European Association for Bronchology and Interventional Pulmonology (EABIP). Specifically, individual experts in the U.K., Greece, Turkey and Romania have expressed their interest and it

<sup>2</sup> Alberg AJ, Brock MV, Ford JG, Samet JM, Spivack SD. Diagnosis and Management of Lung Cancer, 3<sup>rd</sup> Ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *CHEST*. 2013;143(5\_suppl):e1S-e29S.

is anticipated that more groups from across Europe will contact ACCP to become involved in the initiative. Additionally, ASCP has contacted and received a letter of commitment from the European Society of Pathology (ESP). Additional contacts continue to be made with other European organizations and letters of commitment and interest received to date are included in this proposal. Receiving support and advocacy from these organizations and expert leaders will be critical to the success of extending the GAIN initiative into Europe.

Lastly, a survey of European respirologists and pathologists was conducted in May 2013 to assess the current state of practice patterns, testing, and molecular diagnosis of NSCLC.<sup>3</sup> Responses were collected from physicians in Austria, Belgium, France, Germany, Greece, Hungary, Italy, the Netherlands, Slovenia, Spain, Turkey, and the U.K. Two-thirds (68%) of the respirology respondents and 44% of pathologists reported that communication among the patient care team is “sometimes to always” a challenge. Inadequate lung tissue samples were deemed common problems; 72% of respondents indicated that the biopsy sample is often too small and 67% indicated that the number of tumor cells in the biopsy sample is often insufficient for analysis. When asked about who orders histology or biomarker tests, responses were split evenly among respirologists and pathologists. These and other results from this survey confirm that issues in patterns of care and the molecular diagnosis of lung cancer are similar in the U.S. and Europe, and support potential benefits of extending the GAIN initiative into Europe.

The GAIN Global Initiative will support the improvement of NSCLC diagnosis and treatment as it is contextually relevant in European countries and healthcare systems. To this end, overall project goals include:

- Improve knowledge, performance, and competence of European physicians involved in the assessment and management of NSCLC;
- Implement key elements of the U.S. GAIN curriculum that address clinical practice gaps and transfer learning to improve clinical knowledge, use of appropriate medical technology and performance in practice that optimizes patient assessment, diagnosis and subsequent care delivery; and
- Implement a certified ACCP/ASCP Lung Cancer Educator program using standardized materials, teaching instruments and assessment tools from the GAIN curriculum.

Specifically, the objectives of the initiative are to:

- Address country-specific barriers to achieving optimum care for NSCLC.
  - Compare and contrast by geographical location and site the current coordination among physicians in practice settings that assess and care for patients with suspected lung cancer; and
  - Compare and contrast educational outcomes from participants at geographical sites within Europe and compare aggregate data to data obtained in the U.S.
- Identify challenges to optimal patient care and physician collaboration within healthcare systems.

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<sup>3</sup> ACCP. Data on File.

- Identify common barriers to optimal care for patients with suspected lung cancer by comparing current practice against country-specific evidence-based guideline recommendations;
- Evaluate the availability of current technologies for clinical use, including molecular diagnostics across health care systems;
- Assess using hierarchical linear models (HLM) data analysis the change elements that most influence NSCLC outcomes from the GAIN Global initiative.

## **Technical Approach**

### *Assessment of Need*

Information from the U.S. GAIN program suggests similar benefits are possible by conducting this program in Europe. Lung cancer is the most common cancer in the world with 1,375,000 deaths annually.<sup>4</sup> Five-year survival after a diagnosis of lung cancer is a dismal 16%. Regions with particularly high rates of lung cancer include Central-Eastern and Southern Europe, North America, and Eastern Asia. In men, the highest annual lung cancer incidence rates are in central and eastern Europe and North America (65.7 and 61.2 per 100,000, respectively). In women, the lung cancer incidence rates are highest in North America and northern Europe (35.6 and 21.3 per 100,000, respectively). These patterns are fluid because lung cancer rates will change commensurate with changes in smoking prevalence. In addition to smoking, family history and environmental factors also influence risk for developing lung cancer.<sup>2</sup>

Lung cancer is the leading cause of cancer death in European men, and in the next several years will overtake breast cancer and become the leading cause of cancer death in European women.<sup>5</sup> NSCLC is the most common cell type, accounting for approximately 82% of all lung cancers, with an average 5-year survival rate around 15%, despite current diagnostic and therapeutic efforts.<sup>6,7,8,9</sup> New models of targeted therapies and personalized care are developing, but their use is impeded by gaps in knowledge and practice related to anatomic staging and assessment of genetic molecular markers of specific cancers.

Advances in biopsy procedures and testing of biologic specimens hold promise for an improved outlook in lung cancer. Bronchoscopy has always been a mainstay in acquiring tissue specimens, and in the last decade the diagnostic yield has been enhanced using endobronchial ultrasound (EBUS) to guide a transbronchial needle aspiration (TBNA) of abnormal tissue. EBUS-TBNA has largely replaced surgical biopsy of mediastinal lymph nodes in the staging of lung cancer. Data from the Interventional Bronchoscopy Registry and the Diagnostic Bronchoscopy Registry (U.S.) show that the initial diagnosis of lung cancer was made in 34% of samples from more than 10,000 anatomical sites in a total of 4,483 patients, with around 2% of cases requiring a second bronchoscopy procedure. In a recent survey of barriers to proper

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<sup>4</sup> GLOBCAN. Lung cancer incidence, mortality and prevalence worldwide in 2008: summary. <http://globocan.iarc.fr/factsheet.asp>. Accessed May 6, 2013.

<sup>5</sup> Malvezzi M, Bertuccio P, Levi F, La Vecchia C, Negri E. European cancer mortality predictions for the year 2013. *Ann Oncol*. 2013;24(3):792-800.

<sup>6</sup> Cancer Monthly. Lung Cancer (NSCLC). 2012; [http://www.cancermonthly.com/cancer\\_basics/lung.asp](http://www.cancermonthly.com/cancer_basics/lung.asp). Accessed May 5, 2013.

preparation and storage of NSCLC tissue specimens, almost 50% of pathologists cite lack of an adequate tissue sample, illustrating the need to improve physicians' ability to obtain them. Although the initial studies of EBUS-TBNA focused on evaluating diagnostic performance, many of these studies, conducted at centers with considerable experience, also reported impressively low complication rates. Whether these results can be generalized to everyday clinical practice is unknown because the study sample sizes are often too small for a formal analysis of complications. Additional outcomes data on EBUS-TBNA complications in everyday clinical practice are, therefore, needed to establish benchmarks for quality improvement and clinical effectiveness. Bronchoscopy registries are well suited for this purpose because they provide a more generalized snapshot of outcomes and clinical effectiveness than do clinical trials, which by their nature are more selective and not necessarily reflective of everyday practice.

The use of ACCP's AQuIRE program to evaluate EBUS-TBNA complications, their clinical consequences, and the relationship between complications and practice patterns is an ideal means to determine clinical relevance. The data show that EBUS-TBNA is a reassuringly safe procedure with an overall complication rate of only 0.9% in participating centers. The complications noted were most often secondary to concurrent transbronchial lung biopsy (TBBx). Escalations in level of care resulting from these complications were more frequent in older patients, inpatients, and patients receiving deep sedation or general anesthesia. There was significant inter-hospital variation in the use of rapid onsite cytologic evaluation (ROSE) as well as TBBx with EBUS-TBNA. This finding is important because it was able to demonstrate that the use of ROSE for EBUS-TBNA resulted in fewer TBBxs. Current analyses add to the existing body of evidence regarding bronchoscopic complications. It was found that most of the risk in EBUS-TBNA procedures came from concurrent TBBx procedures rather than from the EBUS-TBNA itself. TBBx was performed under fluoroscopy in most cases, but this was left to the individual centers. Because the rate of TBBx and associated pneumothorax was low, no significant difference could be ascertained regarding the impact of fluoroscopy. The incidence of pneumothorax when TBBxs were performed in addition to EBUS-TBNA was 1.8%, which is similar to previous reports.<sup>7</sup>

The GAIN project in the U.S. confirmed that bronchoscopy with EBUS-TBNA is recognized as an important procedure, but there is considerable variability in training, experience, competence and availability of the equipment. GAIN participants expressed the need for change in training and application of the procedure in their practice during and following their participation in the GAIN educational summits.

European physicians are reporting the same challenges. Portuguese experts emphasized the essential diagnostic role of bronchoscopy and the importance of thorough training, stating, "The bronchoscopic procedure requires specific training and experience in both flexible and

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<sup>7</sup> Eapen GA, Shah AM, Lei X, et al. Complications, consequences, and practice patterns of endobronchial ultrasound-guided transbronchial needle aspiration: Results of the AQuIRE Registry. *Chest*;2013;144(4):1044-1053.

rigid bronchoscopy...Diagnostic yield depends on the location, size, character of the border of the lesion, and the ability to perform all sampling methods.”<sup>8</sup>

Likewise, pathologists must become proficient in new methods to characterize NSCLC not only by histology, but also by genetics and molecular biology. Philip T. Cagle, MD, FCAP, and co-chair for new guidelines on molecular testing for lung cancer co-supported by the International Association for the Study of Lung Cancer (IASLC), notes that, “The advent of molecular pathology means that the pathologist now has a very new role in terms of selecting the patients who may benefit from these new therapies.”<sup>9</sup>, Dr. Maureen Zakowski noted “the pathologist’s primary role is to identify the type of tumor that a patient has, and to stage that patient. In addition, the pathologist must be prepared to forward that tissue on for studies beyond the light microscope that will further enable the physicians to administer the appropriate therapy.”<sup>10</sup>

There is a compelling need for coordinated care among the disciplines addressing NSCLC, including pulmonologists, pathologists, medical oncologists, thoracic surgeons, primary care physicians, quality improvement (QI) professionals, and the continuing education providers. Physicians must have the knowledge and procedural skills to provide suitable biopsies for assessment of molecular markers by the pathologists.

Until recently, lung cancer was treated as a homogenous disease with all NSCLCs treated identically, solely on the basis of clinical stage. Based on research, the treatment of lung cancer has been refined, with treatments allocated according to histology and specific molecular features. However, the development of new targeted therapies is, partly, highly dependent on an improved understanding of the molecular underpinnings of tumor initiation and progression, knowledge of the role of molecular aberrations in disease progression, and the development of highly reproducible platforms for high-throughput biomarker discovery and testing.<sup>11</sup>

In summary, issues in the diagnosis of NSCLC are similar in the U.S. and in Europe. It follows that the learning needs of physicians in Europe are likely to be similar. Effective education that is sustainable, with the potential to improve practice and patient outcomes, calls for application of effective educational vehicles. One survey of 180 healthcare providers across Europe showed that they preferred a combination of live and web-based educational interventions in CME activities; they received CME credit approximately 21% of the time through live activities such

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<sup>8</sup> António Saraiva and Christopher Oliveira (2012). Lung Cancer - CT Vs Bronchoscopy, Global Perspectives on Bronchoscopy, Dr. Sai P. Haranath (Ed.), ISBN: 978-953-51-0642-5, InTech, <http://www.intechopen.com/books/global-perspectives-on-bronchoscopy/lung-pathology-ct-vs-bronchoscopy>. Accessed May 6, 2013.

<sup>9</sup> Lung cancer biomarkers guideline -- a pathologist's perspective. April 3, 2013. <http://www.youtube.com/watch?v=auaSKsn9Cz0>. Accessed May 7, 2013.

<sup>10</sup> Zakowski MF. Defining the Pathologist's Role in the Modern, Integrated Management of Advanced NSCLC: From Personalized Medicine to Frontline and Maintenance Therapy. 2011; [http://www.peerviewpress.com/program\\_content\\_page?program\\_id=8915](http://www.peerviewpress.com/program_content_page?program_id=8915). Accessed May 20, 2013.

<sup>11</sup> Nana-Sinkman SP, Powell CA. Diagnosis and Management of Lung Cancer, 3<sup>rd</sup> Ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest*. 2013;143(5\_suppl):e30S-e39S.

as workshops or courses, 19% through online/web-based education, and 27% through international congresses run by associations, organizations, or medical societies.<sup>12</sup> The interventions proposed for the GAIN Global Initiative are delivered in formats that collectively reflect how approximately 67% of CME credit is received by healthcare professionals in Europe.

### *Learning Objectives*

Upon completion of the activities, participants in Europe should be able to:

- Describe the increasing use of tumor biomarkers and targeted therapy in the personalized care of patients with NSCLC. (All in NSCLC healthcare team)
- Demonstrate the knowledge and skills required to obtain an adequate tissue sample for NSCLC diagnosis and classification. (Respirology)
- Identify the current biomarkers used to categorize molecular and histologic features of NSCLC and their relevant applications for diagnosis, monitoring, and personalized care. (Pathology)
- Develop and implement an interdisciplinary coordinated care plan for patients with NSCLC. (All in NSCLC healthcare team)

### *Target Audiences*

The primary target audiences are respirologists and pathologists. Secondary target audiences include oncologists, thoracic surgeons, and other members of the NSCLC management team.

### *Intervention Design and Methods*

ACCP will lead a team of core collaborators in the execution of an integrated initiative for an interdisciplinary team of target audiences that will:

- Support self-assessment of current knowledge, competence, skills, and associated barriers for the diagnosis and management of NSCLC in Europe, integrating a flipped learning pedagogical model with the on-site education being focused upon the GAIN breakout session educational interventions.
- Use a learning management system (LMS) to provide educational materials along with pre-site learning assessments and gap identification to support a learner-centric delivery while assessing overall performance improvement.
- Collect educational outcomes within an established platform and technical framework to track improvements in knowledge, competence, and performance, through the use of check lists for hands-on simulations tools, enhanced case-based and gamification exercises with iPad APPs and other tools in collaboration with ACCP's partner, Applied Measurement Professionals (AMP).
- Disseminate educational findings with the broader community through live presentations, brief synopses or press releases surrounding interim analysis, and formal publications of final outcomes.

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<sup>12</sup> EPG Health Media. Focus Group Report: Continuing Medical Education (CME): The behavior, demands, and views of healthcare professionals in Europe. 2012.

**Expert Steering Committee**—An Expert Steering Committee will be formed to guide the development of this extension project. This Committee will be composed of content experts who represent the target audiences and the varying regions in Europe where the education will be provided. The role of the Expert Steering Committee will be to direct the overall development of the project, ensure that the goals and learning objectives identified for the education are met, and to serve as experts available for consultation and guidance on content development. The Expert Steering Committee will meet in person to begin planning after the grant is approved.

**Systems Analysis Survey**—To modify the GAIN curriculum for the European audience, the first step of the project will be to conduct a larger survey in sites across Europe to identify current practices in NSCLC diagnosis. This survey will be based on results from the May 2013 feasibility study conducted for this proposal. The purpose of the second survey will be to:

- Identify physician knowledge and skills including physicians' knowledge, experience, and skills in obtaining proper tissue samples, and use of current molecular diagnostic tests;
- To determine health systems-based barriers, including local criteria for referral to experienced sites for tissue acquisition and analysis, and the identification of barriers to interdisciplinary communication;
- To better understand the local/regional context in which the physicians must operate, include diagnosis and treatment guidelines.

The results of this survey will be used to contextualize and localize the educational interventions as well as provide data to assess education and program impact and outcomes.

**GAIN Curriculum Updates**—It is expected that the GAIN curriculum components will be updated based on the results of the U.S. program as well as the results from the Systems Analysis Survey. The curriculum will be updated to reflect the *2013 ACCP Evidence-Based Lung Cancer Guidelines, 3<sup>rd</sup> Edition*, published in *CHEST*, May 2013, Volume 143, Number 5. These updated guidelines include a comprehensive and rigorous review of lung cancer literature, and provide graded recommendations to inform practice for the diagnosis and treatment of patients with NSCLC. Additionally, the GAIN curriculum will include recent guidelines from the European Society for Medical Oncology and American Society of Clinical Oncology (ASCO) and will be adapted to reflect local/regional professional and regulatory requirements in the management of patients with NSCLC. A number of additional guidelines will affect the GAIN curriculum including the European Society for Medical Oncology guidelines for early-stage and locally advanced non-metastatic NSCLC and metastatic NSCLC, the ASCO Clinical Practice Guideline Update on Chemotherapy for Stage IV Non-Small Cell Lung Cancer, the ASCO Provisional Clinical Opinion: Epidermal Growth Factor Receptor (EGFR) Mutation Testing for Patients with Advanced Non-Small Cell Lung Cancer Considering First-Line EGFR Tyrosine-Kinase Inhibitor (TKI) Therapy and the Cancer Care Ontario Program and the ASCO Guideline for Adjuvant Chemotherapy and Adjuvant Radiation Therapy for Stages I-III A Resectable Non-Small Cell Lung Cancer.

It is important to note that ACCP recognizes that countries in Europe may have varying guidelines and policy recommendations by which physicians must follow. Careful consideration will be taken to ensure that local/regional guideline requirements will be taken into account when modifying the curriculum for that area.

Updates for the GAIN Global Initiative will also incorporate a “flipped learning” model. This is a pedagogical model in which the typical lecture and elements of a course are reversed, and emphasizes engagement of each participant through an LMS before and after the live educational opportunity (described below) using a variety of technologies. Short video lectures are viewed by participants prior to the onsite session so that during the live education time is devoted to the small breakout sessions, hands-on simulation and case- and problem-based discussions. The video lecture is often seen as the key ingredient in the flipped approach. The notion of a flipped classroom draws on such concepts as active learning, participant engagement, hybrid course design, and course podcasting. The value of a flipped educational model is in the repurposing of time into a workshop where participants can inquire further with content experts, test their existing skills in applying new knowledge, and interact with one another in hands-on activities.

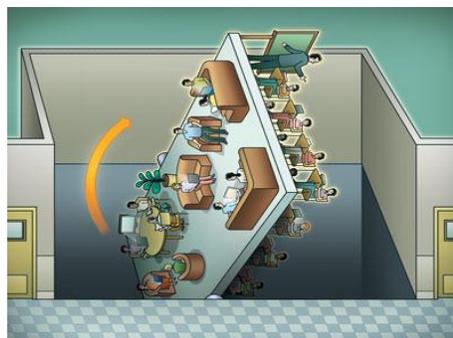


Illustration by Peter Hoey

All curricular and educational resources will be accessed through the ACCP LMS.

**Beta-Test Summit**— An initial beta-test Summit was helpful in the U.S. program to ensure that the curriculum was appropriate for the intended target audience in the context of cultural variables and achieves its learning objectives using the current instructional design methods. A similar beta-test will be conducted for the GAIN Global Initiative. Following the beta-test Summit, improvements to the agenda and curriculum tools will be made to ensure the subsequent European Summits are meet the learners’ educational needs and yield measurably improved educational outcomes.

**10 Live Summits**—After the curriculum is established, a series of 10 live Summits will be held at sites across Europe. This proposal includes communications from leading physicians and organizations expressing interest in conducting these Summits if the program is funded. Sites will be selected based on a review of applications and demonstration that the applicants promote the advancement of care of NSCLC patients through interprofessional collaboration and embrace success across education, leadership and practice. Successful applicants will show evidence of supporting quality, innovative health care practices and delivery across diverse populations.

Each Summit will consist of 6 faculty experts (3 U.S.-based and 3 local) who will deliver content in multiple formats, including lecture, interactive simulations, and interdisciplinary problem-based workshops. The France Foundation will assist with overall project management including

content development, regional participation, venue selection, faculty liaison, participant recruitment, event implementation, delivery of enduring materials, and collection of evaluative outcomes. A proposed agenda and structure for the Summits is provided below, based on the U.S. GAIN experience. The precise schedule and consideration of local/regional language translations (primary language will be English) will vary based upon area sensitivities and cultural appropriateness to optimize the learning goals of this project.

#### Up to Five Weeks Pre-Summit Work

Completed in ACCP LMS:

1. Demographic data questions
2. Pre-meeting confidence rating questions
3. Pre-meeting knowledge assessment questions
4. Short series didactic lectures
5. Pre-reading of selected scientific articles and evidence based guidelines
6. Case-based exercises

#### On-Site Summit Agenda

7:45–8:15 AM	Breakfast
8:15–8:30 AM	Welcome and Introduction
8:30–9:30 AM	Review and responses to results and questions identified in the preliminary work conducted in the Learning Management System
9:30–10:30 AM	Breakout Sessions #1, #2 and #3 #1 Interactive Bronchoscopy Simulations, or Pathology Image Review #2 Problem-Based Learning (PBL) Case Discussions #3 Critical Interprofessional Collaborations to Improve Care
10:30–10:50 AM	Mid-Morning Break
10:50–11:50 AM	Breakout Sessions #1, #2 and #3 #1 Interactive Bronchoscopy Simulations, or Pathology Image Review #2 Problem-Based Learning (PBL) Case Discussions #3 Critical Interprofessional Collaborations to Improve Care
11:50 – 12:30 PM	Group Question and Answers with Faculty
12:30–1:30 PM	Lunch
1:30–2:30 PM	Breakout Sessions #1, #2 and #3 #1 Interactive Bronchoscopy Simulations or Pathology Image Review #2 Problem-Based Learning (PBL) Case Discussions #3 Critical Interprofessional Collaborations to Improve Care

2:30–3:15 PM	Panel Discussion along with Q & A
3:15–3:45 PM	LMS exercise for group
3:45 – 4:30 PM	Next Action Steps and Instructions on how to obtain “ACCP/ASCP Certification as a Lung Cancer Educator”
4:30 PM	Adjourn

Initial Post-Summit Follow Up (2 weeks following date of live activity)

Completed in ACCP LMS:

1. Satisfaction survey data
2. Post-meeting confidence rating questions
3. Post-meeting knowledge assessment questions

Intermediate Post-Summit Follow Up (5 weeks following date of live activity)

Completed in ACCP LMS:

1. Case study exercises
2. Scientific article(s) and evidence based guideline articles reinforcement
3. Reminder of change management plan and highlights of common barriers identified

Final Post-Summit Follow Up (12 weeks following date of live activity)

Completed in ACCP LMS:

1. Live and archived Webinar for each regional summit participants

Respirologists will be asked to collect data on bronchoscopies performed before and after participation in the educational interventions, providing a metric to evaluate the impact of GAIN on actual practice.

**Postgraduate Courses (CHEST World Congress 2014)**—Following the 10 Summits, ACCP will conduct a 1-day Postgraduate Course at the “CHEST World Congress” in Madrid, Spain in March 2014. A second Postgraduate Course will be held at another large Congress meeting in Europe. ACCP currently is in discussions with a specific Congress and will confirm their participation upon initiation of the project. This advanced certification course and examination will be offered to the participants of the Summits, and each participant will receive a modest stipend to cover travel expenses.

Upon successful completion of the Postgraduate Courses, all participants who complete the Europe GAIN training and who submit their own data into the ACCP LMS will be offered the opportunity to receive an ACCP/ASCP certification as a Lung Cancer Educator, or similar designation. ACCP will engage Applied Measurement Professionals to administer and report results of a knowledge and skills-based assessment instrument to determine successful completion of this certification process at the Postgraduate Courses.

**Courses Conducted by Certified Lung Cancer Educators**—To further the reach and provide sustainability for the program, each Certified Lung Cancer Educator will be encouraged to return to their regions and administer one educational program to local and regional physicians. These educators will be provided with a nominal stipend or other incentive for completing the program, which includes entering outcomes and evaluation data into the ACCP LMS site (see below).

**ACCP LMS and Other Online Learning Opportunities**—The ACCP LMS will be the central hosting site for data collection, analysis and storing curriculum components and data for the GAIN Global Initiative. Additionally, ACCP will integrate its AQuIRE database into the execution of this initiative. The ACCP AQuIRE Registry combines data collection, quality and data reporting, and pathways to targeted education to increase knowledge and performance in deficient areas. Participation provides physicians with the ability to improve their practice through the use of data reports and peer comparisons. The ACCP AQuIRE Registry will allow initiative participants with a tool to monitor their practices and understand how they compare with their peers.

In addition to ACCP's LMS, ASCP will update the CheckPath NSCLC Assessment Simulations for Pathologists and develop 4 online interactive case studies. ASCP will also leverage the newly acquired *Labs Are Vital* website which is an international lab website created in Europe.

*CheckPath*: CheckPath is a glass-slide and virtual image based assessment program. CheckPath is among the most popular assessment programs offered at ASCP. In 2011 Pathologists completed over 2,200 CheckPath assessments for 11,052 credits. CheckPath online uses an innovative virtual microscope permitting extensive image manipulation and annotation and assessment feedback is provided by individual, institution, and peer comparison. For this extension, ASCP will update 10 NSCLC online cases with clinical histories.

*Online Interactive Case Studies*: Four (4) online interactive case studies will be developed with consideration to the European pathology audience. The cases will be designed to challenge the participant to apply information they have learned from the GAIN curriculum into their work environments. The online cases study tutorials will provide pathologists with an opportunity to diagnose real NSCLC cases and receive feedback from expert mentors.

*Labs Are Vital Website*: Labs Are Vital is a website used extensively in Europe. The objective of the website is to communicate essential information to laboratory professionals in order to promote safe and effective patient care. ASCP will leverage this website to promote the availability of the curriculum as well as link to appropriate pathology-based educational opportunities.

#### *Evaluation Design*

Evaluation for this initiative includes both formative and summative evaluations of the project's outcomes and implementation. Two distinct assessment components will compose the project evaluation: 1) the assessment of education and support activities; 2) the assessment of project outcomes and implementation. Outcomes will be measured for individuals participating in the

program, as well as for each location. The following table lists the outcome levels, what will be measured, some specific data that will be collected, and measurement tools that will be employed to evaluate the various deliverables described within this request:

**Project Outcomes and Measurement Tools**

<b>Outcome Level</b>	<b>What will be measured</b>	<b>Data to be Collected</b>	<b>Measurement Tools</b>
Level 1: Participation	Number of Participants	Total # of participants  Demographic info for participants	Participation Records  Evaluation Surveys
Level 2: Satisfaction	Degree to which expectations of participants are met	% of participants indicating appropriate content level  % of participants who indicate the learning objectives are met	Evaluation surveys
Level 3a: Learning - Declarative knowledge	Degree to which participants state how to do what the activity intended them to know	Baseline levels of knowledge  Improvement in procedural knowledge over baseline in post activity	Multiple choice questionnaire for pre- and post-medical context
Level 3b: Learning Procedural knowledge	Degree to the which participants state what the activity intended them to do	Documentation of intent to change clinical practice  Creation of implementation plan	“Intent to change form”
Level 4: Competence	Attestation of intent to change clinical practice	Documentation of specific aspects of practice change	Intent to change form, including a checklist of practice-based changes  3-month Post-survey
Level 5: Performance	The degree to which the participants do in practice what the activity intended.  The degree to which participants recognize and address systems barriers	Examination or Assessments Activities  Post-survey	CheckPath  3-month post-survey

The results of the evaluation will be used to assess satisfaction with the project (Levels 1 and 2) and changes in physician skills, knowledge, and competence related to the education content (Levels 3a, 3b, and 4) over the course of the project. **After completion of the project, changes in Performance (Level 5) will be assessed through an outcomes survey that will assess changes and improvement in practice.** The implementation of this project does not offer adequate time to assess changes in patient or community health (Level 6 and 7) at the end of this project. Overall, systems change will be analyzed via a 3-month post- assessment, using t-test and HLM to assess systems change.

*Analysis and Communication of Results:* ACCP and its collaborators will collect outcomes data for each initiative described in this proposal. Data will be analyzed at designated intervals and appropriate adjustments will be made to content and execution. A complete set of outcomes data will be analyzed at the conclusion of initiative implementation and the final results will be delivered in a detailed report. It is expected that the final outcomes report will contain the following analysis, among other aspects:

- Summary of learner participation – including demographics
- Faculty Participation – including demographics
- Linkages between outcomes collected, initial clinical gaps identified, learning objectives, and desired results
- Assessment of improvements in participant knowledge, competence, and performance
- Assessment of overall systems change and country-specific barriers change using HLM and other outcomes assessment
- Unbiased analysis of tactical execution and learnings that supported implementation of improvements over the course of initiative
- 360 degree analysis from all relevant stakeholders as to the value of the initiative
  - Participants (evaluative surveys)
  - Faculty (surveys and interviews)
  - Educational collaborators (surveys and interviews)

*Broader Dissemination of Results:* ACCP and the collaborators acknowledge the value of reporting educational outcomes to the broader community of continuing education and beyond. To this end, outcomes data will be disseminated and published through various, established channels. These may include:

- Live Presentations at relevant meetings
- Brief synopses or press releases surrounding interim analysis through available channels
- Formal publications of final outcomes analysis in relevant journals

### **Detailed Work Plan**

Q2 2013: If the GAIN Global Initiative is funded, it will begin in the summer of 2013 with a planning meeting among the collaborators. The goal of the meeting is to ensure that the overall framework, details, and general timelines are confirmed and in place for this initiative. It will also be an opportunity to suggest faculty for the Expert Steering Committee which will meet in person late summer/early fall. Additionally, sites will be identified for the Summits.

Q3 2013: The systems analysis survey will be developed by ASCP and deployed by both ASCP and ACCP. At the same time The France Foundation will work with the identified sites for the Summits on logistics planning. Following the completion of the systems analysis survey, the curriculum will be modified as needed and uploaded to the ACCP LMS.

Q4 2013: The beta test Summit will be held and the curriculum content will be modified as needed. The 10 Summits will be completed Q4 2013 and Q1 2014. At the same time, ACCP will be developing the content with Applied Management Professionals for the Postgraduate Course(s) planned for 2014.

Q1 2014: The 10 Summits will be completed and the first of the 2 Postgraduate Courses will be held. Data collection and analysis will begin on the evaluations and outcomes of the Summits.

Q2 2014: The second of the 2 Postgraduate courses will be held. Individual courses to be held by the Certified Lung Cancer Educators will begin.

Q3 and Q4 2014: ACCP and the collaborators will work together to collect, assess, and create an outcomes document for this project. Lastly, a plan to disseminate the results of the project will commence.

## Deliverables Schedule

ACTIVITY/DELIVERABLE/MILESTONE	2013			2014			
	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Conference call and planning among collaborators							
Expert Steering Committee invited							
Expert Steering Committee meeting confirmed							
Site identification and recruitment							
Live Expert Steering Committee held							
Systems-based assessment survey developed							
Systems-based assessment survey deployed							
Systems-based assessment results compiled/analyzed							
Curriculum modifications made							
Summit logistics confirmed							
LMS development and launch							
Planning for Postgraduate Course(s)							
Summits implemented							
Postgraduate Course(s) held							
Individual courses conducted by Certified Lung Cancer Educators							
Collection of final program data							
Analysis of program data							
Final outcomes report delivered							
Dissemination of project results							