Global Bridges/Pfizer IGLC European Grant Program

A. Cover Page

1. Title: Category 1 – Development and evaluation of STAR - an expert digital platform supporting training and delivery of cessation interventions by healthcare professionals.

Grant ID: 25672387

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2. Abstract

Background: Access to smoking cessation treatment, and particularly dedicated stop smoking services, is limited in many countries. Digital tools could support healthcare professionals (HCPs) with limited training and resources to deliver evidence-based cessation treatment to their patients.

Overall goal: To develop, evaluate and disseminate the STAR (Smoking Treatment Advisory Resource) Programme – a novel internet-based platform acting as a support tool and expert system for data gathering, delivery of evidence-based treatment, networking, and training for HCPs offering cessation treatment.

Target population: The main target group are HCPs in Poland, with a particular focus on HCPs treating patients with tobacco-related diseases.

Methods: The project comprises three main phases. Phase 1 will be devoted to development of STAR, including consultations with HCPs and patients who smoke. Phase 2 will involve mixed-methods evaluation of STAR. Finally, during Phase 3 the STAR Programme will be refined based on results from Phase 2 and promoted among a wider community of HCPs and patients, and the results disseminated.

Assessment: Evaluation will involve quantitative assessments of changes in key indicators (e.g. practice, knowledge, attitudes, self-efficacy) from baseline to immediate post-training and at 6 month follow-up; analysis of STAR usage data; as well as qualitative evaluation (e.g. before and after interviews with participating HCPs).

Expected outcomes: It is expected that the project will result in the development of an acceptable and sustainable Programme that will increase the number of HCPs delivering evidence-based cessation support. STAR will offer possibilities for further development, and adaptation for other settings and countries.
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C. Reviewer Comments.

Please briefly describe how you addressed any review panel comments you were provided following their review of your letter of intent.

Our Letter of Intent has not received any comments from the reviewers.
D. Main Section of the proposal

1. Overall Goal & Objectives

   The overall goal of the project is to develop, evaluate and disseminate an internet-based STAR (Smoking Treatment Advisory Resource) Programme – a platform which will act as a support tool and expert system for training, delivery of evidence-based treatment, data gathering, and networking for healthcare professionals (HCPs) offering cessation treatment. The project aims to address the gaps in training and provision of smoking cessation support in a context where access to face-to-face training and specialist stop smoking services are limited, with a particular focus on Poland.

   This project is closely aligned with this RFP’s focus. We aim to increase engagement of HCPs in delivering cessation support, and to create an off-the-shelf, simple and sustainable solution that is exportable to other countries and settings. Such platform would be accessible to a broad range of HCPs, and will focus on capacity building (both knowledge and skills), as well as outcome and process monitoring.

   The project is also aligned with the mission, past research endeavours, and expertise accumulated by the three applicant organizations. Both the Health Promotion Foundation (HPF) and the National Centre for Smoking Cessation and Training (NCSCT) are devoted to training and supporting healthcare professionals to deliver evidence-based cessation support. One of the principal goals of the UCL Tobacco and Alcohol Research Group (UTARG) is to evaluate and improve cessation services and programs, and to identify and disseminate knowledge on effective components and best practice in smoking cessation. Both NCSCT and UTARG have also been employing and researching digitally-based support for smoking cessation, e.g. web-based trainings developed by NCSCT, and web-based and smartphone-based stop smoking support to smokers.

   The specific objectives for this project are:

   1. To carry out formative research to identify the specific needs of HCPs with regards to their ability to offer cessation treatment in a context where specialist cessation services are limited, and how to support them best using digital tools.

   2. To systematically develop the STAR Programme that:

      2.1. initially targets Polish HCPs, but can be adapted to different settings and countries, and further developed in the future;

      2.2. consists of an internet-based platform that meets the needs of HCPs, is accessible on computers and mobile devices (including smartphones), and serves four main functions: training and ongoing professional development, support delivery of evidence-based and continuous cessation treatment to patients (including automated support following discharge from care or hospital), data collection and outcome monitoring, and networking.

   3. To evaluate the STAR Programme, its individual components, as well as its implementation strategies through quantitative and qualitative methods among up to 300 HCPs in Poland, and to disseminate the findings.
4. To refine STAR based on these findings, and to promote it among HCPs and patients in Poland and abroad.
5. To expand the network of healthcare professionals involved in smoking cessation, and to create an alliance of professionals that are supported by the Programme in Poland.

2. **Current Assessment of need in target area.**

There are currently over 8 million daily smokers in Poland (33% of the male, and 20% of the female population), with more than half interested in quitting and having tried to quit in the past [1, 2]. However, contrary to best clinical practice and Framework Convention on Tobacco Control guidelines, smoking cessation is not routinely offered to patients who smoke, and access to cessation clinics and behavioural support is limited. For example, only eight stop smoking clinics were listed as currently operating in Poland (data from the Polish National Quitline Service, March 2016). According to statistics on cessation support that is reimbursed by the national health system in Poland, in 2014 just over nine thousand smokers in Poland were assessed for smoking status and offered advice to quit, and fewer than 2500 smokers accessed dedicated stop smoking support services, which in case of some voivodeships (regions) was fewer than 40 [3]. Although this is likely an underestimation of all smokers accessing cessation support in Poland, the figure is much lower than the number of smokers who access cessation services in the England (almost 590 000 in the same time period), where similar numbers of smokers live [4].

The current gap and need for creation of the STAR Programme have been further identified through observations and involvement of the project members in delivery of cessation training and treatment in the UK and Poland, a review of the current training delivered in Poland and its assessment against NCSCT training and best practice guidelines on smoking cessation from UK and US, and finally, through consultations with the clinicians involved in tobacco control and cessation in Poland.

Moreover, since 1991 HPF has worked to disseminate best practice in treatment of tobacco dependence in Poland. However, to date such training has only been conducted locally, lasted just one day, and focused on knowledge development rather than wider capacity building and skill development, such as planning a quit attempt and offering support with relapse prevention. Moreover, only basic printed materials were offered to attendees for use post-training. No database system or additional tools were created to further update, support and connect professionals delivering cessation treatment with their patients or colleagues. Currently, no program of training and support in smoking cessation exists in Poland that could be scaled up and offered remotely to interested HCPs, and there are very few clinics to which patients could be referred to for additional advice and support.
Finally, the concept of hybrid interventions, where digital tools support clinicians and advisors, are seen as the future of smoking cessation [5]. Importantly, digital tools could help to address many of the barriers identified. Research indicates that healthcare professionals face numerous barriers to treatment provision in various countries and settings [6, 7], many of which could be addressed by the implementation of digital tools. However, very little is still known about what digitally-based cessation support would be acceptable, relevant and feasible for HCPs to implement in their practice, in Poland and in other countries. Therefore, this project will also help to address this important gap in literature.

3. **Target Audience**

The project is targeting practicing HCPs in Poland, who represent a range of specialties in which the delivery of smoking cessation support could be particularly relevant and impactful. The primary audience for the Project are secondary care physicians who are treating patients with tobacco-related diseases, i.e. cardiologists, pulmonologists, neurologists and oncologists. We also aim to engage and provide STAR to any HCPs with the capacity to offer cessation support to a wider population of patients: general practitioners, dentists, midwives, and nurses. Recently, nurses in Poland have been provided with an opportunity to prescribe medication, and thus may become an especially important group of HCPs that could be involved in cessation efforts.

There are almost 500,000 physicians, nurses and midwives in Poland, all of whom could benefit from using the STAR Programme. The Programme could also be beneficial to HCPs from other specialties, and future efforts could be focused on adapting the Programme further to meet their needs.

Between 20 and 30 healthcare professionals representing the target specialties will be involved in the Programme development and consultations. A further 200 to 300 HCPs representing different target groups across Poland will be recruited for the core evaluation of the Programme (Phase 2). Dissemination of the final version of the STAR Program will be conducted on a national scale.

Additionally, the project will also involve smokers as a second target and end-user group for the STAR Program. Around 20 smokers will be recruited as part of formative research to identify their needs with regards to the support that they could receive as part of STAR.

*a. Describe the level of commitment from the potential participants including your plan for recruitment as necessary.*

To date the annual trainings on tobacco dependence treatment and the Tobacco or Health Conference have been popular and well-attended by HCPs in Poland (from 30 to 300 attendees per training and 100-300 attendees at conferences; source: HPF Internal Documentation). However, the overall reach and scope of such trainings has been limited, as
outlined in section 2. Following consultations within the teams from HPF, NCSCT and UTARG, as well as HCPs in Poland we have identified an interest in the current project, as well as a readiness to support recruitment efforts.

We have planned for how to engage and recruit the target groups of healthcare professionals during all phases of the project. Multiple channels will be employed at each stage to ensure wide promotion.

For Phase 1 (consultations and formative research as part of Programme development, as well as identification of local champions) we will recruit participants through (a) professional networks of individuals that will act as medical advisors and consultants on this project, (b) contact lists created during previous cessation trainings and annual Tobacco or Health conferences that are organized by HPF; and (c) through HPF’s contacts within university and general hospitals in Krakow, Warsaw, Wroclaw, Opole and Kalisz, and Polish medical, and nurses’ associations.

During Phases 2 and 3 (Program evaluation and dissemination), in addition to the above channels, we will also distribute promotional information (e.g. in the form of sponsored articles and advertisements) in the main medical newsletters, magazines and internet portals for HCPs in Poland. Experience of HPF members in recruitment suggests that these channels are effective at reaching potential participants across clinical specialties nationwide. We will also set up a project website with complete information and enrolment procedures, as well as establish presence on social media in Poland, all of which will support engagement with the media, information dissemination, and automatic recruitment into Phase 2 (evaluation).

b. Demonstrate the scope of your target audience has a potential to impact the goal established in this proposal.

Each stage of the project and the recruitment strategy are designed to engage representatives of the target populations. This will ensure that we reach our goal of creating tools that will be relevant, acceptable, and suitable for the clinical environment in which they could be used in the future.

By engaging members of the key clinical specialties from the early stages of the project we will begin to build networks and identify future champions who will support the dissemination of STAR during the course of the project, and after its completion. Through targeting several groups of HCPs we hope to build infrastructure and capacity to support many groups of patients who smoke in Poland. Finally, through broader promotional campaigns and activity on social media we also hope to raise awareness among patients regarding the STAR Program and available cessation support, which may further help with disseminating and adopting it after project completion.
c. Describe who will directly benefit from the project outcomes. Include in this description whom, beyond the primary target, would potentially benefit from the project in terms of this being a model for others to replicate or expand.

The primary beneficiaries of the project will be patients who smoke, who will obtain access to evidence-based cessation support. Even brief advice from HCPs was shown to increase the number of quit attempts made, and consequently also quit rates [8, 9]. The support provided to smokers by HCPs participating in the project is intended to be more intensive and extended, which could further increase the expected success rates [10].

The participating HCPs will also benefit directly through skill and knowledge development, as well as improvements in self-efficacy, capability, opportunity, motivation and readiness to deliver cessation treatment [11, 12]. They will also gain access to a tailored and interactive expert system that will support them in delivering cessation treatment and monitoring their patients and outcomes, as well as networking with other healthcare professionals.

This project will also result in the creation of smoking cessation tools and evaluation materials that could be used and adapted by other organizations and in other settings. This in turn will foster future cross-country collaborations and initiatives, and further support capacity building efforts at national and international levels.

Finally, the project will contribute to research literature on digital smoking cessation programs and tools aiding clinicians. The project outcomes will help to inform future ‘hybrid’ programs involving digital tools supporting HCPs providing treatment for tobacco dependence, which are seen as an important element of smoking cessation programs in the future [5]. The findings will be especially informative for countries and settings where access to dedicated smoking cessation services is limited.

4. Project Design and Methods

a. Include a description of the overall strategy, methodology and analysis linking them to the goal of the project.

The project will build on the experience and work conducted to date by participating organizations, and employ mixed-methods to systematically develop and evaluate the STAR Programme. Data collection and evaluation are integral to all aspects of the project, which will enable us to assess in a more comprehensive manner the potential impact and role of the Programme in delivery of smoking cessation treatment by HCPs. The work will be spread across three Phases:

Phase 1 will be devoted to Programme development and creation of infrastructure for its evaluation (e.g. securing ethical approvals). All tools and modules within STAR will be based on evidence and best clinical practice from UK and US [13, 14]. The training modules of STAR
will be based on the materials developed by NCSCT, and will be supplemented by additional content tailored to the target medical specialties. The training will focus on fostering competences shown to be important for smoking cessation [15] as well as developing HCPs’ skills in delivery of support of different intensity, depending on their time availability: 5As, very brief advice (VBA), and additional behaviour change techniques (BCTs), or active ingredients [16], that were demonstrated to be effective in cessation treatment among smokers [17, 18] and when delivered in stop smoking services [19].

The development of STAR will follow (i) UK Medical Research Council guidelines on complex intervention development [20], (ii) guidelines on developing theory- and evidence-based interventions that are based on COM-B model of behaviour, which stands for capability, opportunity and motivation as key influences on behaviour [21], as well as (iii) guidelines on development of digital healthcare interventions [22]. All three emphasise the importance of conducting formative research, use of qualitative methodology, adoption of a person-centred perspective (i.e. engaging end-users in the development process), and conducting of user-testing sessions during development of digital interventions [23]. These methods aim to identify specific needs and expectations of the target population, and help to ensure that the resulting Programme will be attractive, acceptable and relevant to them.

Phase 2 will involve mixed-methods evaluation of the Program and data analysis.

Finally, during Phase 3 we will refine STAR based on findings from Phase 2, prepare publications, and disseminate findings and the Programme in Poland, and promote it in other countries.

b. Describe the way the project planned addresses the established need and produces the desired results.

STAR Program will meet the needs for training and treatment provision by supplying HCPs with the following tools and features:

i. interactive training based on evidence and best practice from the UK and US, with a focus on competence and knowledge development, motivation boosting and addressing of barriers to treatment implementation, and tailored to different medical settings and specialities (initial focus on: (i) secondary care physicians treating: CVD, stroke, COPD, and cancer; (ii) dentists; (iii) nurses and midwives; and (iv) general practitioners/family doctors);

ii. integral features supporting delivery of personalized cessation treatment during daily clinical practice, including setting up of quit attempts, provision of behavioural support, support with medication selection and adherence to pharmacotherapy, as well as ongoing and automated support for relapse prevention and medication use offered via email, text or other acceptable method.

iii. features providing remote and ongoing support and monitoring of patients who are attempting to quit, as well as enabling data and outcome collection;

iv. networking and practice exchange tools for healthcare professionals;
v. a searchable database of cessation advisors trained with the Programme accessible to other healthcare professionals and patients.

Features ii-v will be unlocked after users complete the training module within STAR, and the accompanying post-training assessment.

STAR Programme will offer an opportunity to provide best practice training and sustainable development in cessation treatment for the first time to a much wider audience of HCPs in Poland. A key innovation is that STAR will provide tools available post-training and assisting HCPs to introduce evidence-based treatment in their practice, with particular focus on addressing limited time and other barriers to implementation that they may face [7]. The new tools will also help them to connect with their patients and colleagues, and monitor the progress and outcomes of their efforts, which could act as important source of feedback and motivation to continue with treatment delivery and training. Finally, the STAR Programme aims to facilitate and extend smoking cessation treatment beyond the immediate contact with patients, which is seen as important elements of effective cessation support [10, 14].

Importantly, the Programme will be developed in a way to facilitate modification of content, addition of new modules, and translation and adaptation to other countries and settings.

c. Indicate how you will determine if the target audience was fully engaged in the project.

The data collection and assessments planned will enable us to evaluate the extent to which the target audience was engaged in the project. First, data on engagement with and usage of STAR itself will be collected automatically and remotely (e.g. data on individual registrations, completion of individual sessions, use by clinicians of different specialties). This will help us to assess uptake, retention, and adherence to the program. Second, we will have data from all completed assessments, which will collect data on additional measures of engagement, e.g. context in which the Program was found most useful [24].

Thirdly, we will supplement the quantitative assessments with qualitative evaluation of process data involving semi-structured telephone interviews with a sub-sample of evaluation participants. This will further help to identify any additional facilitators and barriers, and to evaluate the processes that will allow us to appropriately interpret the final results, including those pertaining to engagement. Finally, during Phase 3 involving wider dissemination of the project we will be able to assess the uptake and retention in the Programme among the wider community of HCPs in Poland, and continue to monitor data from Programme use.

d. Include a description of the measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.

We have consulted the published literature and guidelines, conducted online searchers, and discussed the project within the project team as well as with other researchers, clinicians and
cessation advisors in Poland and abroad. We are not aware of any such programme being available or in development in Poland or other European countries, particularly with the functionality and scope of the STAR Programme.

For example, several different online trainings have been developed to date, particularly in English (e.g. those created by NCSCT), but these tend not to provide additional digital tools that could help clinicians to implement smoking cessation in their daily practice, or to monitor their patients’ progress and outcomes. There has also been some research on computerized clinical decision support systems, for example in the US, which were shown to improve processes and practitioner performance, with some evidence for improvements in health outcomes [25, 26]. Such programs were also shown to have promising outcomes in smoking cessation [27-29]. However, the programs developed to date primarily tended to have limited functionality, such as offering reminders to offer care, or support patient assessment, and facilitate making referrals to specialists services [28, 30-32][33]. Such programmes also tended to be embedded within local computer systems and databases, e.g. in specific hospitals [28, 29], which is limiting their adaptation to other settings.

To our knowledge no programme created to date would offer comprehensive functionality, be web-based, accessible on smartphones, and contain both clinician-facing and smoker-facing components [33]. Moreover, we believe that our project is innovative, not only because it aims to develop several unique tools for supporting HCPs and patient monitoring, but also because it incorporates educational, interventional, and research components (including a comprehensive evaluation that will enable us to improve the STAR Programme), and involves healthcare professionals in all stages of the project.

The concept of hybrid interventions is promising but still relatively new. We still lack insights on the needs of healthcare professionals with regards to provision of cessation support using digital tools. Our project will therefore address the limitations identified in current treatment provisions, as well as important gaps in the literature and practice of developing and implementing digitally-supported cessation programs in clinical practice.

e. If appropriate, show how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.

This project builds on, and considerably extends the existing programs of training delivered by HPF and NCSCT, as well as NCSCT’s and UTARG’s work on developing and evaluating face-to-face and digital stop smoking interventions. First, over the past three decades HPF has developed a range of materials to support HCPs in delivering treatment for tobacco dependence, including face-to-face trainings and published materials (e.g. leaflets and Consensus on the Diagnostics and Treatment of Tobacco Dependence [34, 35]). Simple online trainings in brief and very brief advice for nurses and midwives, and pharmacists have also been in development by the HPF.
Secondly, NCSCT has developed a range of online and face-to-face training resources for cessation advisors and health and social care professionals in the UK (www.ncsct.co.uk), which will be adapted for STAR. However, none of these offered additional digital tools supporting the delivery of cessation support in daily practice.

Furthermore, over the past few years the UTARG team has been working on several projects involving evaluation of cessation services and training [11, 19, 36-40], as well as the development (including formative research) and evaluation of digital tools, such as websites and smartphone apps that support cessation among smokers [41-45], including smartphone-based interventions for craving management and adherence to stop smoking medications (projects currently led by Aleksandra Herbec). The group has also worked on development of tools, such as taxonomies of behaviour change techniques (BCTs), active ingredients that could be used in cessation interventions [16, 17, 19], and guidelines for development and evaluation of behaviour change interventions [21, 22]. The insights and materials developed as part of these projects will be used to inform the new STAR Programme and its evaluation.

Our Programme will therefore build on these existing tools, as well as adapt them further to the needs of HCPs in Poland. Finally, the outcomes of research on effectiveness of cessation training and interventions conducted by NCSCT and UTARG to date will provide foundations for evidence-based content and advice offered within STAR.

f. If your project includes the development of tools note if they be available publically at no cost.

One of our goals is to ensure that the Program could be sustained in the future, and accessible at no cost for use to as many HCPs and patients as possible, and available for other researchers to develop further. As part of the project and consultations we will also explore acceptable, appropriate and suitable solutions to ensure that we could continue to offer technical and maintenance support to this programme for long-term use, as well as to continue updating and adapting it, where necessary.

5. Evaluation Design

a. In terms of the metrics used to assess the need for this project, describe how you will determine if the practice gap was addressed for the target group.

The STAR Programme and the impact it has on improving the gap in smoking cessation training and treatment provision will be evaluated using mixed-methods, including (a) structured online surveys, (b) semi-structured qualitative interviews, and (c) analysis of data automatically collected through STAR. This approach will allow us to triangulate the data and gain better understanding of the findings [46]. The findings will inform refinement of STAR before its wider dissemination. The following data will be collected:
Quantitative assessments during Phase 2 (main evaluation of STAR)

- Baseline characteristics of participating CHPs (e.g. age, medical specialty, experience with delivery of cessation treatment to date) to assess the reach and uptake of STAR across medical specialties
- Changes in self-assessments from baseline, to immediate post-training and at long-term (6 month) follow-up in key determinants of cessation treatment behaviour comprised within COM-B model (standing for capability, opportunity and motivation [47]), and including changes in knowledge, self-efficacy, confidence, willingness, motivation and readiness to offer support. Data will be collected through structured online surveys adapted from NCSCT assessments [37] and previous evaluations of similar trainings (e.g. [11] and supplemented by surveys assessing constructs within the COM-B model [21, 47])
- Changes from baseline to 6 month follow-up in participating HCPs’ practice (e.g. self-reported number of patients treated, adherence to best practice cessation support)
- Effectiveness and adherence to the STAR Programme assessed in terms of number of treatments and patients registered, number of quit dates set, parameters of quit attempts (e.g. use of cessation medications), self-reported abstinence rates among registered smokers;
- Uptake, adherence and retention of STAR, as well as other quantitative indices of STAR usage that will be collected automatically (e.g. number of sessions and logins, use of individual features)
- Satisfaction from STAR Programme and its individual features (e.g. training, features for smokers)
- Assessment of potential confounders (e.g. access to other cessation training and support during STAR use)
- Assessment of barriers and facilitators to use the STAR Programme and implement cessation treatment in daily practice

Quantitative assessment during Phase 3 (dissemination)

- Baseline characteristics of users
- Uptake, usage, adherence and retention of the Program

Steps will be taken to support data collection from the Programme after completion of the current project, to enable ongoing and long-term monitoring and evaluation.

Quantitative data analysis

All data analysis will be pre-planned, consulted with a statistician at UTARG (Dr Emma Beard), conducted in appropriate statistical packages (SPSS or R), and registered on the Open Science Framework. The data collected will help to answer a number of key questions, including:

a) What are the characteristics of the users of the STAR Programme?

Descriptive statistics will be calculated, including means (an SD’s) for continuous variables and percentages (and N’s) for categorical variables. Where appropriate, 95% confidence intervals will also be derived.
b) What are the patterns of use of the STAR Programme, including retention?
Usage will be ascertained using a mixture of descriptive statistics and regression-based analyses. Latent growth curve modelling using a multilevel approach will give an indication of changes in usage measures and retention overtime. For analysis of usage data, a composite score will also be derived to reflect all usage components (e.g. number of sessions and logins, use of individual features) using a combination of multiple correspondence and principle components analysis. This will give a better indication of the predictors of usage, as it will reflect the multifaceted nature of the measure.

c) What baseline characteristics predict outcomes of interest, as well as usage and retention of STAR?

d) What is the impact of the STAR Programme on practice and key outcomes, in terms of changes from baseline to immediate and long-term follow-up?
We will use multiple linear and logistic regression to predict the outcomes of interest and usage and retention patterns, whilst controlling for confounding variables. If required, multilevel modeling will be used to account for individual clustering (i.e. repeated measures) and structural clustering (e.g. participants being from similar geographical areas or clinics).

For all analyses statistical assumptions will be assessed and violations dealt with using traditional methods e.g. robust regression for outliers and transformations for non-linear/non-normality. Multiple imputation will be considered for missing data.

Qualitative assessment:
Qualitative methodology will be used during Programme development and evaluation at 6 months follow-up. This will involve semi-structured face-to-face and telephone interviews and focus groups with key stakeholders and HCPs. The qualitative study at follow-up will explore in more detail the impact and role of STAR, process variables, as well as barriers and facilitators of using STAR and providing cessation support. The interviews will be semi-structured and will also address the constructs of the COM-B model [21, 47] (i.e. capability, opportunity and motivation in relation to use of STAR and delivery of cessation support). All qualitative studies will be audio-recorded, transcribed verbatim and analysed using appropriate qualitative methods (Thematic Analysis and Framework Analysis; [48])

• how you will determine if the results evaluated are directly related to the intervention described in this proposal

This project aims to develop STAR, and then to refine it based on the findings from the evaluation phase. Therefore, evaluation will be done through an observational, within-subject design and focus on assessing changes in key indicators from baseline to post-training and then at long-term follow-up (6 months). Although this design does not involve a control group, we believe that we will be able to attribute the changes observed to the exposure and use of STAR. This is because HCPs participating in the study will be unlikely to receive any other training in smoking cessation and interventions at the time, and no other changes in provision of care and cessation treatment to patients are anticipated. We will monitor the situation and assess at
baseline and follow-up the context in which participants enroll into the study and use STAR (e.g. access to other training or changes to local tobacco control measures and regulations).

The effectiveness of the final, refined STAR Program at improving quit rates among smokers could be evaluated in a large randomized controlled trial in the future.

Quantify the amount of change expected from this project in terms of your target audience (e.g., a 10% increase over baseline or a decrease in utilization from baseline between 20-40%)

Based on previous research on training of smoking cessation among HCPs we expect that the program will lead to improvements in all outcomes from baseline to follow-ups, including knowledge, skills and provision of support. The improvements from baseline are expected to last until long-term follow-up, and to be in the magnitude of at least 20% in scores on such items as knowledge, confidence, and motivation [12, 37].

All HCPs are expected to increase the number of patients whom they offer face-to-face evidence-based cessation advice. The self-reported number of patients provided with such advice is expected to at least double, and even increase 20-fold since baseline (e.g. HCPs who never routinely offer support are expected to deliver it to at least 20 new patients on average during the 6 month of participating in the study, depending on the size of their patient population who smoke). It is also expected the participating HCPs will register with STAR on average at least 10 smokers, who will then be undergoing quit attempts supported by patient-facing components of STAR. The self-reported adherence to provision of individual elements of this evidence-based support (e.g. assessing smoking status, recommending setting up of a quit date, providing advice on pharmacotherapy) is expected to be between 50-80% [12].

Therefore, using conservative estimates, the number of smokers offered evidence-based support through STAR could reach over 2000 (e.g. 200 HCPs participating in Phase 2, each offering support to 10 smokers on average). Such numbers would almost match the total number of smokers treated in specialist services in Poland in 2014 [3].

We also expect high satisfaction ratings from STAR program among HCPs given that it will be developed in consultation with the representatives of the target users.

Finally, during nation-wide dissemination in Phase 3 (planned for the last 2-3 months of the project) we expect that at least 300 new HCPs will register to use STAR, and that interest to use the program will be growing.

b. Describe how you plan for the project outcomes to be broadly disseminated.

One of the key goals of this project is to disseminate the findings, as well as to promote the final version of the STAR Programme among HCPs and patients in Poland, and abroad. We therefore plan to dedicate the last three months of the project to support activities that will ensure wide promotion.
First, the findings will be disseminated among the academic community through articles in peer-reviewed international journals (e.g. Addiction, Journal for Nicotine and Tobacco Research) and at international conferences (e.g. SRNT and SRNT Europe, World Conference on Tobacco or Health, Conference for Behavioural Medicine in the UK and US). We will aim to publish at least 2 open access manuscripts. Secondly, the findings and insights will also be disseminated through articles in Polish general and medical press, relevant scientific and social media, as well as and through the Global Bridges network. Finally, the STAR Programme will be promoted among wider group of HCPs through printed and online articles, leaflets and online mailing lists, as well as through attendance and presentations at medical conferences in Poland.

6. Detailed Workplan and Deliverables Schedule

The current project is planned to be completed within 24 months, which includes STAR Programme development, evaluation and dissemination. We have been advised by the Grant Officer to accommodate few months for finalizing contracts in case of obtaining funding for this project, and therefore we plan for the project to start in November 2016. The specific deliverables and timelines are presented in Table 1 below. To ensure the project starts on time, some steps, e.g. start of recruitment of an assistant and confirmation of engagement from medical champions, would initiate soon after obtaining a positive decision on the funding of this project. Development of the STAR Programme should be accomplished within 6-8 months, but we have planned a 2 month buffer in case of any delays.

The first 10-11 months of the project (Phase 1) will be devoted to (a) preparation of infrastructure for the planned studies and data collection, and simultaneously to (b) formative research and systematic development of STAR. Before commencing data collection we will finalize all study protocols and assessment materisl, and secure appropriate approvals from research ethics committees. We will also recruit and engage around 10 local healthcare champions representing different medical specialties, who will support our recruitment efforts and study promotion, for example by promoting the project in their institutions, medical organizations and regions in Poland. Finally around months 9-10 we will prepare all necessary study promotion materials (e.g. project website, leaflets, advertisements, content for newsletters) that will be used in Phase 2.

At the same time (months 1-11) we will work on the development of the STAR Programme. STAR Programme development will involve consultations and needs assessment among the target groups of HCPs, as well as translation and adaptation of current NCSCT and HPF materials. These activities are planned to finish by the 5th month. Around the months 8-9 we will be conduct user testing of the of the STAR to identify any issues and improve user experience before recruitment into Phase 2 starts.
Phase 2 of the project will start around the 11th month of the study (with recruitment into the study) and last until the 23rd month (completion of data analysis), and will focus on mixed-methods evaluation of the Programme. Between months 11-14 we will conduct recruitment of HCPs, baseline assessment, initiation of training through the Programme, and complete the immediate post-training assessment. During months 18-20 we will conduct the main follow-up assessments (both quantitative and qualitative). For individual participants these assessments will take place 6 months after enrolment. Additionally, we will conduct automated and ongoing data collection on STAR usage (from the moment it will be used by HCPs around 11th month of the project), supplemented by intermittent assessment of process data among a sub-sample of participants (e.g. use qualitative methods to assess adherence and identify any emerging barriers and challenges to implementation). Data analysis is planned to take place between months 18 and 23.

Finally, Phase 3 (STAR Programme refinement and dissemination) will take place between months 17 and 24. The refinement of the STAR Programme will be informed by the results from Phase 2, and is planned to last up to two months (between 20th-21st month), after which it will be promoted among HCPs in Poland. We will continue to monitor update and usage of the Programme until the end of the Project, and steps will be taken to ensure that this monitoring continues after this project finishes. Manuscripts for publication will be prepared between months 17 and 24. Findings will be disseminated at international and national conferences at the earliest opportunity.
Table 1: List of the deliverables and a schedule for completion of each deliverable.

<table>
<thead>
<tr>
<th>Deliverables</th>
<th>Schedule for completion: Months of the Project (Nov ’16 – Nov ’18)</th>
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</thead>
<tbody>
<tr>
<td><strong>Phase 1 (Setting up study infrastructure)</strong></td>
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<tr>
<td>Employing Technical Research Assistant</td>
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<tr>
<td>Finalization of study protocols and materials</td>
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<tr>
<td>Securing ethical approvals for formative research</td>
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<tr>
<td>Securing ethical approvals for STAR evaluation (Phase 2)</td>
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<tr>
<td>Recruiting and training of local champions</td>
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<tr>
<td>Development of promotional and recruitment materials</td>
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<tr>
<td>Start of promotion of STAR Programme among HCPs</td>
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<tr>
<td><strong>Phase 1 (STAR Programme Development)</strong></td>
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<tr>
<td>Formative research (needs assessment and consultations)</td>
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<tr>
<td>Adaptation of existing NCSCT HPF materials</td>
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<tr>
<td>Development and internal testing of STAR Programme</td>
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<td>User-testing of STAR Programme</td>
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<td>Release of STAR Programme for Phase 2</td>
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<tr>
<td><strong>Phase 2 (Evaluation)</strong></td>
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<tr>
<td>Recruitment and baseline assessment</td>
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<tr>
<td>Pre- and immediate post-training evaluation</td>
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<tr>
<td>Ongoing collection of data on STAR Programme use</td>
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<tr>
<td>Process evaluation (including qualitative)</td>
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<td>6 month follow-up: quantitative assessment</td>
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<tr>
<td>6 month follow-up: qualitative evaluation</td>
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<tr>
<td>Data analysis</td>
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<tr>
<td><strong>Phase 3 (Programme refinement and dissemination)</strong></td>
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<tr>
<td>Preparation of publications</td>
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<tr>
<td>STAR Programme refinement based on findings from Phase 2</td>
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<tr>
<td>Nation-wide release for Poland</td>
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<tr>
<td>Dissemination in Poland and Europe</td>
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</tbody>
</table>

1 Including assessments, and materials for formative research
2 Formative research will include expert consultations and interviews using qualitative methodology
3 Including Project website, leaflets, and advertisement materials
E. References

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