TB and Tobacco

Tobacco cessation within TB programmes: A 'real world' solution for countries with dual burden of disease.

Grant Agreement no. 680995

Collaborative Project
EU H2020 Programme
Health
Medical Research and the Challenge of Ageing

Project duration: 1st November 2015 to 31st October 2019 (48 months)

Deliverable 2.2
"All Approvals Package"

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Workpackage: 2
Workpackage Leader: Prof. Kamran Siddiqi (University of York)

Due date: 31st October 2016 (Project month 12)
Actual submission date: 31st March 2017 (Project month 17)

Dissemination Level: Public
Revision: 1.0

This project has received funding from the European Union's Horizon 2020 Research and Innovation programme, under Grant Agreement number 680995.

Contents

TB and Tobacco – 680995 **Deliverable 2.2** **March 2017**

1. Introduction

The TB and Tobacco project is centred on a clinical trial of cytisine; a tobacco cessation drug which partially mimics the effects of nicotine. In this study, cytisine will be offered to TB patients who smoke, as part of a smoking cessation strategy including behavioural support.
The cytisine trial makes up Work Package 2 (WP2) of the TB and Tobacco project.
The original proposal was to conduct the trial in 3 South Asian countries – Nepal, Pakistan and Bangladesh.

2. D2.2 Requirements

Deliverable D2.2 comprises an 'All Approvals Package' for the cytisine trial.
UK Ethics Committee approval was received on 12th February 2016 from the Health Sciences Research Governance Committee (HSRGC) at the University of York, as described in the report for Deliverable D2.1 (Submissions Package).
To fulfil the D2.2 requirements, the All Approvals package needs to include:
a) Ethics approval letters from the national competent authorities for the trial countries,
b) Approval letters from the respective national TB programmes (NTP) in the 3 trial countries,
c) Approval letters from the respective Drug Regulatory Authorities, for importing the pharmaceutical agents (cytisine and placebo) used in the trial.

3. D2.2 Timelines

The original deadline set out in the Description of Action for completion of D2.2 was project month 12 (October 31st 2016). However, because of delays in receiving approvals from the competent authorities, this deadline was extended (with the permission of the Project Officer) to 31st January 2017, with a further requested extension to month 17 (31st March 2017).
The above delays have affected Milestone MS11 (Trial recruitment start); the proposed date of which has changed from month 13 to month 19 (May 2017). Consequently, MS12, MS13 and MS14 have been pushed forward 6 months each. Deliverables D2.3 (Report on the Trial), D2.4 (Tobacco use scale) and D3.1 (Cost-effectiveness analysis) have also been delayed by 6 months, respectively. However, no impact on other Work Packages is predicted by these delays. At the time of writing it is still expected that the trial and data analysis will be completed within the time (and budget) available.

4. Fulfilment of D2.2 Requirements

Local teams in the 3 trial countries worked hard from the start of the project to secure written approvals from the relevant authorities in their respective countries.

4.1 Pakistan

a) The National Bioethics Committee (NBC) in Pakistan issued ethics approval on 6th June 2016.
b) NTP Pakistan is a partner (no.4) in the TB and Tobacco consortium, working with The Initiative (Partner no.5) to implement the trial in Pakistan.
A letter of support for the project was sent from NTP to the Drug Regulatory Authority of Pakistan on 3rd June 2016.
c) The Drug Regulatory Authority of Pakistan (DRAP) issued approval on 1st December 2016.

4.2 Bangladesh

a) The National Research Ethics Committee (NREC) of the Bangladesh Medical Research Council (BMRC) issued approval on 31st August 2016.
b) Approval from the Bangladesh NTP was obtained on 12th November 2015.

c) The Bangladesh Directorate General of Drug Administration issued approval on 21st March 2017 (following a new regulation stipulated in January 2017 that required re-submission of all previously submitted documents).

4.3 Nepal

Negotiations between the HERD International team (HERDi; TB and Tobacco Partner no. 10, in Nepal) and the ethics committees at the Nepal Health Research Council (NHRC) and Institutional Review Board (IRB) were on-going from December 2015 until January 2017. In the week commencing 16th January 2017, HERDi were disappointed to learn that ethics approval for the cytisine trial was unlikely to be granted. The consortium agreed not to appeal this decision because it would cause further delays to the trial start date. Instead, the research strategy was changed. (See Section 5, below).

5. Adjustment to research strategy.

Following the negative decision of the Nepal ethics committee, the TB and Tobacco partners agreed to abandon the cytisine trial (WP2 and WP3) in Nepal, and increase patient recruitment in Bangladesh to compensate.
Other Work Packages (WP1, WP4, WP5 & WP6; concerning development and implementation of a behavioural support package), are to continue in Nepal.
The above changes are detailed in an Amendment to the Grant Agreement, accepted by the EU on 23rd March 2017.

6. Approval letters

The Approval letters described above are attached to this document, in the following order:
6.1 Ethics Approval for Pakistan
6.2 NTP Approval letter for Pakistan
6.3 Drug Regulatory Authority Approval for Pakistan
6.4 Ethics Approval for Bangladesh
6.5 NTP Approval letter for Bangladesh
6.6 Drug Regulatory Authority Approval for Bangladesh.

National Bioethics Committee (NBC) Pakistan

Ref: No.4-87/16/NBC-200 Part -B/RDC/ 4197 **Date: 6th June, 2016**

Dr. Razia Fatima
Research Coordinator
National TB Control Program
Block E & F, EPI Building, Near NIH
Islamabad.

Subject: **Tobacco cessation within TB programmes: A 'real world' solution for countries with dual burden of disease (WP2, WP3, and WP4) (Part B of series NBC-200).**

Dear Dr. Razia Fatima,

I am pleased to inform you that the above mentioned project has been cleared by "Research Ethics Committee of the National Bioethics Committee".

Kindly keep the National Bioethics Committee Secretariat updated with the progress of the project and submit the formal final report on completion.

Yours sincerely

(Prof Dr. Aasim Ahmad)
Chairman
NBC-Research Ethics Committee

NBC Secretariat:
Pakistan Medical Research Council, Shahrah-e-Jamhuriat, Off Constitution Avenue, Sector G-5/2, Islamabad
www.nbcpakistan.org.pk, www.pmrc.org.pk, e-mail: nbcpakistan.org@gmail.com, pmrc.rdc@gmail.com Tel: 92-51- 9207386, 9206092, Fax 9216774

Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
NATIONAL TB CONTROL PROGRAM

3rd June, 2016

Executive Director (DRAP),

Subject: **Adverse effects monitoring mechanism for Research study "Tobacco cessation within TB programs: A 'real world' solution for countries with dual burden of disease"**

The National Tuberculosis Program (NTP) as a principal investigator (PI), in collaboration with "The initiative" and university of York UK, is implementing a research project involving Tuberculosis Patients using Tobacco in the following selected sites;

1. Samli Sanitorium, Murree
2. PIMS Hospital, Islamabad
3. TB Hospital, Rawalpindi
4. Gulab Devi Hospital, Lahore
5. Infectious Disease Hospital Bilal Gunj, Lahore
6. Mayo Hospital, Lahore
7. LRH, Peshawar
8. DHQ Hospital, Bannu
9. TB Hospital, Sargodha

This study will be carried out as a multi-centre two-arm, double-blind placebo controlled trial to assess the effect of Cytisine drug with behavioral support intervention. The aim of the study is to reduce the burden of tobacco-related lung diseases and the approach is to integrate inexpensive tobacco cessation strategies of proven efficacy into TB control programs. This has three advantages: a) Preventing non-communicable diseases as well as reducing TB-related deaths; b) TB patients are more likely to quit tobacco than healthy smokers – 'teachable moments'; and c) in the absence of specialist infrastructure, an approach to 'piggyback' cessation on existing programs is a desirable policy imperative. The study has already been approved from Pakistan Medical and Research Council (PMRC). As the Cytisine medicine will be used as an intervention and every medicine has some adverse effects so NTP has nominated the focal person (clinician) which is working under the umbrella of NTP at each site to monitor the adverse effects in patients of the above mentioned drug and report to the "Adverse and side effects monitoring committee for the TB and Tobacco Trial" the committee at national level is constituted as below;

1. Dr. Razia Fatima PI (NTP)
2. Dr. Amina Khan (The Initiative)
3. Dr. Mahboobul Haq (NTP)

Dr Ejaz Qadeer
National Manager
Tuberculosis Control Program

National TB Control Program, Block E&F, EPI building, Near National Institute of Health (NIH) (Prime Minister's National Health Complex), Park Road, Islamabad, Pakistan
Tel: +92 51 843 8077 – 80, Fax: +92 51 843 8081, Email: ntpmanagerpak@ntp.gov.pk, Web: http://www.ntp.gov.pk

F. No. 3-5/2016 DDC (PS)
Government of Pakistan
Drug Regulatory Authority Of Pakistan
Pharmacy Services Division
*****

Islamabad, the 01st December, 2016

"SAY NO TO CORRUPTION"

Dr. Razia Fatima,
Principal Investigator/Research Coordinator,
National TB Control Program,
Islamabad.

SUBJECT: **Tobacco Cessation within TB programmes: A "real world" solution for countries with dual burden of disease. A parallel group, double blind, randomized, placebo-controlled trial.**

I am directed to refer to your letter No. Nil, dated 15th June, 2016, on subject cited above. It is to convey that your request for conducting subject clinical trial at the following centers/hospitals, under strict supervision of Principle Investigator Dr. Razia Fatima and respective research associates, has been acceded to by the Registration Board in its 262nd meeting held on 20th and 21st October, 2016;

i) Federal Govt. TB Center, Rawalpindi
ii) PIMS Hospital, Islamabad
iii) Gulab Devi Chest Hospital, Lahore
iv) Infectious Disease Hospital, Bilal Gunj, Lahore
v) District Head Quarter Hospital, Bannu
vi) TB Hospital, Sargodha

2. Permission to import the proportionate trial material i.e Desmoxan (Cytisine) Capsules and Placebo in the quantity of 55,000 capsules each, from M/s Alfofarm Farmacja, Sp. z.o.o ul. Partyzancka, 133/151, 95-200 Pabianice, Poland, manufactured by M/s Alfofarm Fabryka, Lekow Sp. z.o.o ul. Szkolna 31, 95-054 Ksawerow, Poland, for the purpose of trial, has also been accorded by the Registration Board.

3. You may approach Assistant Director (I&E), DRAP, Islamabad, for import of trial material as required under the Drugs (Import & Export) Rules, 1976 and get import license accordingly.

4. You are required to submit the report of Clinical Trial of each individual case every month positively. The above permission is being granted subject to the conditions (see over leaf) notified under GCP Guidelines 2008/ICH Guidelines.

5. It is requested to submit Periodic Safety Update Report (PSUR)/Pharmacovigilance Report, if any ADR emerged or reported as per requirement of rules.

01/12/16

(Ahmad Din Ansari)
Deputy Director (PS)

Copy to:

1. Director, Pharmacy Services Division, DRAP, Islamabad
2. The Secretary, Drug Registration Board, DRAP, Islamabad
3. Assistant Director (I&E), DRAP, Islamabad with the advise to furnish the copies of Form-4 & 6, import documents including COA and clearance certificate of each consignment of investigational drug to this office for record.
4. Office file

Conditions for Trial:-

I. The drug (s) so imported shall bear a label to state "For CLINNICAL TRIAL ONLY' AND "NOT FOR SALE".

II. Quarterly report of results obtained during clinical trials shall be furnished to the concerned section of the Drug Regulatory Authority of Pakistan.

III. Ethical Criteria for these trials including Pakistan Good Clinical Practices/ICHGCP/WHO guidelines on the subject shall be fully observed.

IV. Any ADR shall be reported immediately to the Division of Pharmacy Services of the Drug Regulatory Authority of Pakistan.

V. The final result of the trial shall also be communicated to the Drug Regulatory Authority of Pakistan.

VI. The sponsor shall upon request from any nominated officer of the Drug Regulatory Authority of Pakistan at reasonable times permit access to and copy and verify any records and reports relating to the clinical investigation conducted.

VII. The clinical trials and subsequent progress report should contain sufficient information required to access the safety to subjects of the clinical investigations.

VIII. The clinical trials and subsequent progress report should contain sufficient information required to access the safety to subjects of the clinical investigations.

IX. The clinical investigations should not be conducted in a manner substantially different than described in the protocols submitted with the application for approval of the clinical trials.

X. The drug shall not be promoted or distributed for commercial purposes and quantities justified by the requirement of investigational study/clinical trials.

XI. The clinical trials or any amendment or report to the investigational study, shall not contain any intrigue statement of material fact or omit material information required by this part as PGCP/ICH GCP.

XII. On a notice by the Division of Pharmacy Services, Drug Regulatory Authority of Pakistan, the sponsor shall provide written explanation or correction in writing.

XIII. Provision of Institutional Review Board may also be complied with strictly.

XIV. During monitoring, one officer from DRAP shall accompany the monitoring team. The monitoring cell of trial shall intimate DRAP well in time to depute suitable officer to join the monitoring inspection.

XV. The Drug Regulatory Authority may terminate clinical trial approval if:-

a. The sponsor and all investigators fail to promptly investigate and inform the Drug Regulatory Authority of Pakistan for serious or unexpected adverse experiences in accordance with PGCP/ICH GCP or fail to make any other report required under this part.

b. The sponsor fails to submit an accurate progress report of the investigations in accordance with PGCP/ICH GCP.

c. The sponsor fails to comply with any other applicable requirements of the Drugs (Research) Rules, 1978 and PGCP/ICH GCP.

বাংলাদেশ চিকিৎসা গবেষণা পরিষদ
Bangladesh Medical Research Council
BMRC

Ref: BMRC/NREC/2016-2019/1475 Date: 31-08-2016

National Research Ethics Committee

Dr. Rumana Huque
ExecutiveDirector
ARK Foundation
Road#21, House#B130
New DOHS, Mohakhali
Dhaka- 1206.

Subject: Ethical Clearance

With reference to your application on the above subject, this is to inform you that your Proposal entitled **"A Double blind, randomized, placebo controlled trial of Cytisine, a novel tobacco cessation agent, in order to assess feasibility and acceptability of introducing Cytisine along with behavior support (BS) package as tobacco cessation strategies to TB control programme"** has been reviewed and approved by the National Research Ethics Committee (NREC).

You are requested to please note the following ethical guidelines as mentioned at page 2 (overleaf) of this memo-

(Dr. Mahmood-uz-jahan)
Director

BMRC Bhaban, Mohakhali, Dhaka-1212, Bangladesh
Phone: +88 02 9848396, PABX: +88 02 9849311, Fax: +88 02 9848820, E-mail: info@bmrcbd.org, Web: www.bmrcbd.org

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Memorandum of Understanding (MOU)

For Partnership between

National Tuberculosis Control Program (NTP), Directorate General of Health Services (DGHS) and ARK Foundation on the research Project:

"Project name: Tobacco cessation within TB programme: A real world' solution for countries with dual burden of disease"

Parties:

The National Tuberculosis Control Program (NTP), under The Directorate General of Health Services (DGHS), Government of the People's Republic of Bangladesh represented by the Director MBDC and Line Director TB-Leprosy, Mohakhali, Dhaka - 1212, Bangladesh (hereinafter 'NTP Bangladesh')

And

ARK Foundation, House-B130, Road-21, New DOHS, Mohakhali, Dhaka-1206, Bangladesh, herein after called 'ARK Foundation'.

Background

Tobacco consumption and TB are the two 'colliding epidemics' in many low- and middle-income countries (LMICs) that are facing the epidemiological transition between communicable and non-communicable diseases. The two epidemics tend to interact and amplify each other's impact on the outcomes within the affected population. A growing body of evidence demonstrates that tobacco smoking increases the risk of acquiring TB infection and its progression to TB disease. In TB patients, continued smoking leads to poor disease outcomes. A substantial body of evidence exists on the efficacy of a range of pharmacological and behavioural interventions offered by healthcare professionals for tobacco cessation. However, the evidence of effectiveness and cost-effectiveness of offering such interventions to TB patients is almost non-existent. On the other hand, a well-developed TB control programme within a country with high TB incidence and tobacco use, offers a unique opportunity to provide tobacco cessation within TB care and study the effects of its integration within the health system.

Purpose: The main purpose of this project is integrate inexpensive tobacco cessation strategies of proven efficacy (behavioural and pharmacological) within tuberculosis control programmes. In

this proposal we would like to first: (1) assess the effectiveness and cost-effectiveness of tobacco cessation strategies in helping tuberculosis patients who use tobacco to quit and to improve their clinical outcomes - the *effectiveness* goal; and then (2) explore how best to implement these strategies, bring these to scale and sustain over the long term – the *implementation* goal. We intend to achieve these research goals in three countries in Bangladesh, Pakistan and Nepal.

Our specific objectives are as follows:

- To assess the effectiveness and cost-effectiveness of behavioural support for tobacco cessation by measuring biochemically validated continuous abstinence from the target quit day to week 26 and week 52 in TB patients who use tobacco on a daily basis
- To assess any differences in the intervention effect among TB patients between tobacco smokers, smokeless tobacco users and those that use a combination of smoking and smokeless forms of tobacco
- To assess any differences in the intervention effect across, severity of TB, high and low socio-economic status (SES), gender and age sub-groups
- To monitor and follow up of TB patients who are trial participants

We will work in 10 sub-districts, which will be chosen in consultation with relevant government authorities. This will be a three year project starting from December, 2015.

Duration and Renewal

- This MoU will be effective from the date of signing and it will remain valid until December, 2018.
- This MoU can be extended for further scaling up of the project with the consent of all parties concerned in writing.

Terms of Reference for Partnership

- Implementation of the project activities will be according to the agreed project proposal and the project guidelines;
- All activities will be run according to the National TB Control Program's guidelines;
- Collaboration between parties will be guided by mutual respect, trust and recognition of mutual expertise;
- All activities will be organized within the ARK/ Project frame work.

Contribution and roles and responsibilities of the Parties:

National TB Control Program:

The NTP will

- Provide policy guidelines, and regulatory and operational frameworks for the involvement of public and private sector in TB control Program;
- Facilitating basic and refreshers training of the public and private sector providers as per agreed training guidelines;
- Provide necessary policy and logistic support including printed guidelines, case management guidebook, and other ACSM materials;
- Ensure drugs, reagents and other diagnostic equipment as necessary to the designated diagnostic and DOT centers;
- Supervise field activities as per agreed 'Plan of Action' of the project and conducting joint monitoring of the ongoing field activities;
- Liaise with implementing partners as and when required;
- Providing support as when required to ARK and other implementing organizations on various technical issues;
- Review progress of project activities in quarterly review meetings;
- Provide support to ARK Foundation for wider application of partnerships in the National TB Control Program.

It is to be noted that, NTP will not provide any financial support for initiating the above mentioned research project. ARK foundation is solely responsible for any financial support required to initiate the research project. In case, venue is required for providing training at upazila level, necessary approval will be taken from CS & UH&FPO.

ARK Foundation:

The TORs for the ARK will be to:

- Provide additional financial assistance for the activities which are not covered within the National TB Control Program;
- Provide technical assistance to the Project;
- Overall supervision, monitoring, and evaluation of the project activities;
- Provide training to the relevant personnel with an aim to capacity building subject to government policies and approval;
- Coordinate between the NTP and NGOs for project activities &;
- Liaise with other implementing partners as and when required;
- Organize Technical Working Group meetings as and when required as collaboration with the NTP;
- Assist its field office and other implementing organizations on various technical issues and provide support as per the NTP guidelines;

- Implement Field activities as per agreed 'Plan of Action' of the project;
- Monitor progress of the on-going field activities in collaboration with the NTP;
- Collect Field data as per agreed in project proposal in consultation with the NTP;
- Keep records as per the NTP guidelines;
- Ensure reliability of data for research and development of strategic guidelines for future replication in consultation with the NTP;
- Evaluate the project at the end of the project period;
- Disseminate the project outcomes at different levels in collaboration with the NTP;
- Act as policy advocates for wider application of partnerships in the TB Control Program.

Termination of the Contract

Either party can terminate this agreement at any time with sixty days notice in writing indicating reasons for same to the other party. In-kind non-perishable goods received through the project will be returned to the ARK at the point of termination of this agreement.

In case of dispute, final decision will be made by the NTP. All the parties agree to the principles and intentions specified in this MOU and have signed three copies on the dates specified below:

Dr. Md. Mozammel Haque
Director, MBDC &
Line Director, TB-Leprosy
DGHS, Mohakhali, Dhaka.

Signed on behalf of NTP:

Dr. Md. Mozammel Haque
Director, MBDC &
Line Director, TB-Leprosy
DGHS, Mohakhali, Dhaka.

Dr. Md. Mozammel Haque
Director MBDC &
Line Director TB/Leprosy Control Program
Directorate General of Health Services
Mohakhali, Dhaka-1212
Date:

Signed on behalf of ARK:

Rumana Huque

12/11/2015

Dr. Rumana Huque
Executive Director
ARK Foundation

Dr Rumana Huque
Executive Director
ARK Foundation
New DOHS, Mohakhali
Dhaka-1206
Date:

Witness for "NTP"

(Dr. Md. Mojibur Rahman)

Date: 12/11/2015

Witness for "ARK"

12.11.15

Date:

Government of the People's Republic of Bangladesh
Directorate General of Drug Administration
Oushodh Vaban
Mohakhali,
Dhaka-1212, Bangladesh

Memorandum

Memo no:- DGDA/CTP-1/06/2016/4138 Dated: 21.03.2017

To
Dr. Rumana Huque
Principal Investigator of research protocol# ISRCTN- 43811467
ARK Foundation

Subject: Approval of research protocol of "A Double blind, randomized, placebo controlled trial of Cytisine, a novel tobacco cessation agent, in order to assess feasibility and acceptability of introducing Cytisine along with behavior support (BS) package as tobacco cessation strategies to TB control programme".

The research protocol of "A Double blind, randomized, placebo controlled trial of Cytisine, a novel tobacco cessation agent, in order to assess feasibility and acceptability of introducing Cytisine along with behavior support (BS) package as tobacco cessation strategies to TB control programme" is being approved under these conditions:

1. The research protocol is approved for the period of 12 months from the date of approval by DGDA.
2. The DGDA approval shall automatically be revoked after one year if the research is not started. After one year, you shall have to seek approval from DGDA for starting the research.
3. The DGDA should be notified if the said research is discontinued.
4. You should notify DGDA immediately of any serious or unexpected adverse effects or unforeseen events that might affect on participants.
5. You shall obtain prior approval from DGDA for any modification in the approved research protocol and/or approved consent form(s).
6. You shall conduct the study in accordance with the DGDA approved protocol and shall fully comply with GCP guidelines.
7. You shall submit a report for time extension of the protocol (in prescribed from) if you are unable to complete the protocol activities within the time mentioned in the protocol.

8. As principal Investigator, the ultimate responsibility for scientific and ethical conduct including the protection of the rights and welfare of study participants vest upon you. You shall also be responsible for ensuring competence, integrity and ethical conduct of other investigators activities and staffs directly involved in this research. Also ARK foundation shall be responsible for ensuring patient safety and will liaison with the respective authority in case of any severe adverse event. The organization should be responsible for any consequences that arise during the implementation of the trial.
9. You shall recruit/enroll participants for this study strictly adhering to the criteria mentioned in the research protocol.
10. You shall obtain legally effective informed consent (i.e. consent should be free from coercion or undue influence) from the selected study participants or their legally responsible representative, as approved in the protocol, using the approved consent form prior to their enrolment in this study. Before obtaining consent, all prospective study participants must be adequately informed about the purpose(s) of the study, its methods and procedures, risk and benefits, compensation plan, right to participate/ not participate in the study or withdraw from the study.
11. Data and/or samples should be collected and interviews should be conducted as specified in the DGDA approved protocol, and confidentiality must be maintained. Data/samples must be protected by reasonable security, safeguarding against risks such be their loss or unauthorized access, destructions, usage and modification. Data/samples should not be disclosed, made available to or use for purposes other than those specified in the protocol, and shall be preserved for a period, as specified under policies/practices.
12. You have to submit GCP training certificates of all responsible personnel involved with clinical trial before starting this trial.
13. You shall promptly and fully comply with the decision of the DGDA to suspend or withdraw its approval for the research protocol.
14. Important steps in the protocol will be monitored by DGDA during research.
15. DGDA has right to cancell this research approval if any major deviation found during this research.
16. Permission of DGDA is needed to send research sample outside of the country.
17. You have to submit research findings/ results to DGDA.

21/3/17

Major General Md. Mustafizur Rahman,
Director General,
Directorate General of Drug Administration,
Mohakhali,
Dhaka-1212, Bangladesh.
Phone: 9880819
E-mail: dgda.gov.bd@gmail.com.