Clinical Trial Management Common Job Interview Questions With Answers Asked in Interview

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Way to Success

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What Is A Clinical Trial?

Ans : Although there are many definitions of clinical trials, they are generally considered to be biomedical or health-related research studies in human beings that follow a pre-defined protocol. ClinicalTrials.gov includes both interventional and observational types of studies. Interventional studies are those in which the research subjects are assigned by the investigator to a treatment or other intervention, and their outcomes are measured. Observational studies are those in which individuals are observed and their outcomes are measured by the investigators.

Why Participate In A Clinical Trial?

Ans: Participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research.

Who Can Participate In A Clinical Trial?

Ans: All clinical trials have guidelines about who can participate. Using inclusion/exclusion criteria is an important principle of medical research that helps to produce reliable results. The factors that allow someone to participate in a clinical trial are called "inclusion criteria" and those that disallow someone from participating are called "exclusion criteria".

These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. Before joining a clinical trial, a participant must qualify for the study. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy participants. It is important to note that inclusion and exclusion criteria are not used to reject people personally. Instead, the criteria are used to identify appropriate participants and keep them safe. The criteria help ensure that researchers will be able to answer the questions they plan to study.

What Happens During A Clinical Trial?

Ans :

The clinical trial process depends on the kind of trial being conducted. The clinical trial team includes doctors and nurses as well as social workers and other health care professionals. They check the health of the participant at the beginning of the trial, give specific instructions for participating in the trial, monitor the participant carefully during the trial, and stay in touch after the trial is completed.

Some clinical trials involve more tests and doctor visits than the participant would normally have for an illness or condition. For all types of trials, the participant works with a research team. Clinical trial participation is most successful when the protocol is carefully followed and there is frequent contact with the research staff.

Can A Participant Leave A Clinical Trial After It Has Begun?

Answer :

Yes. A participant can leave a clinical trial, at any time. When withdrawing from the trial, the participant should let the research team know about it, and the reasons for leaving the study.

What Are The Benefits And Risks Of Participating In A Clinical Trial?

Answer :

Benefits:

Clinical trials that are well-designed and well-executed are the best approach for eligible participants to:

Play an active role in their own health care.

Gain access to new research treatments before they are widely available.

Obtain expert medical care at leading health care facilities during the trial.

Help others by contributing to medical research.

Risks:

There are risks to clinical trials.

There may be unpleasant, serious or even life-threatening side effects to experimental treatment.

The experimental treatment may not be effective for the participant.

The protocol may require more of their time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements.

What Are Side Effects And Adverse Reactions?

Answer :

Side effects are any undesired actions or effects of the experimental drug or treatment. Negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental treatments must be evaluated for both immediate and long-term side effects.

How Is The Safety Of The Participant Protected?

Answer :

The ethical and legal codes that govern medical practice also apply to clinical trials. In addition, most clinical research is federally regulated with built in safeguards to protect the participants. The trial follows a carefully controlled protocol, a study plan which details what researchers will do in the study. As a clinical trial progresses, researchers report the results of the trial at scientific meetings, to medical journals, and to various government agencies. Individual participants' names will remain secret and will not be mentioned in these reports.

Does A Participant Continue To Work With A Primary Health Care Provider While In A Trial?

Answer :

Yes. Most clinical trials provide short-term treatments related to a designated illness or condition, but do not provide extended or complete primary health care. In addition, by having the health care provider work with the research team, the participant can ensure that other medications or treatments will not conflict with the protocol.

Where Do The Ideas For Trials Come From?

Answer :

Ideas for clinical trials usually come from researchers. After researchers test new therapies or procedures in the laboratory and in animal studies, the experimental treatments with the most promising laboratory results are moved into clinical trials. During a trial, more and more information is gained about an experimental treatment, its risks and how well it may or may not work.

What Is A Protocol?

Answer :

A protocol is a study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

What Is A Placebo?

Answer :

A placebo is an inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the experimental treatment's effectiveness. In some studies, the participants in the control group will receive a placebo instead of an active drug or experimental treatment.

What Are The Different Types Of Clinical Trials?

Answer :

Treatment trials test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

Prevention trials look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes.

Diagnostic trials are conducted to find better tests or procedures for diagnosing a particular disease or condition.

Screening trials test the best way to detect certain diseases or health conditions.

Quality of Life trials (or Supportive Care trials) explore ways to improve comfort and the quality of life for individuals with a chronic illness.

What Is "expanded Access"?

Answer :

Expanded access is a means by which manufacturers make investigational new drugs available, under certain circumstances, to treat a patient(s) with a serious disease or condition who cannot participate in a controlled clinical trial.

Most human use of investigational new drugs takes place in controlled clinical trials conducted to assess the safety and efficacy of new drugs. Data from these trials are used to determine whether a drug is safe and effective, and serve as the basis for the drug marketing application. Sometimes, patients do not qualify for these controlled trials because of other health problems, age, or other factors, or are otherwise unable to enroll in such trials (e.g., a patient may not live sufficiently close to a clinical trial site).

For patients who cannot participate in a clinical trial of an investigational drug, but have a serious disease or condition that may benefit from treatment with the drug,FDA regulations enable manufacturers of such drugs to provide those patients access to the drug under certain situations, known as "expanded access." For example, the drug cannot expose patients to unreasonable risks given the severity of the disease to be treated and the patient does not have any other satisfactory therapeutic options (e.g., an approved drug that could be used to treat the patient's disease or condition). The manufacturer must be willing to make the drug available for expanded access use. The primary intent of expanded access is to provide treatment for a patient's disease or condition, rather than to collect data about the study drug.

Some investigational drugs are available for treatment use from pharmaceutical manufacturers through expanded access programs listed in ClinicalTrials.gov. If you or a loved one is interested in treatment with an investigational drug under an expanded access protocol listed in ClinicalTrials.gov, review the protocol eligibility criteria and inquire at the Contact Information number. If there is not an expanded access protocol listed in ClinicalTrials.gov, you or your health care provider may contact a manufacturer of an investigational drug directly to ask about expanded access programs.

Describe The Phases Of Clinical Trials?

Answer :

These are the following four phases of the clinical trials:

Phase 1: Test a new drug or treatment to a small group of people (20-80) to evaluate its safety.

Phase 2: The experimental drug or treatment is given to a large group of people (100-300) to see that the drug is effective or not for that treatment.

Phase 3: The experimental drug or treatment is given to a large group of people (1000-3000) to see its effectiveness, monitor side effects and compare it to commonly used treatments.

Phase 4: The 4 phase study includes the post marketing studies including the drug's risk, benefits etc.

What Is A Control Or Control Group?

Answer :

A control is the standard by which experimental observations are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo.

Describe The Validation Procedure? How Would You Perform The Validation For Tlg As Well As Analysis Data Set?

Answer :

Validation procedure is used to check the output of the SAS program generated by the source programmer. In this process validator write the program and generate the output. If this output is same as the output generated by the SAS programmer's output then the program is considered to be valid. We can perform this validation for TLG by checking the output manually and for analysis data set it can be done using PROC COMPARE.

How Would You Perform The Validation For The Listing, Which Has 400 Pages?

Answer :

It is not possible to perform the validation for the listing having 400 pages manually. To do this, we convert the listing in data sets by using PROC RTF and then after that we can compare it by using PROC COMPARE.

Can You Use Proc Compare To Validate Listings? Why?

Answer :

Yes, we can use PROC COMPARE to validate the listing because if there are many entries (pages) in the listings then it is not possible to check them manually. So in this condition we use PROC COMPARE to validate the listings.

How Would You Generate Tables, Listings And Graphs?

Answer :

We can generate the listings by using the PROC REPORT. Similarly we can create the tables by using PROC FREQ, PROC MEANS, and PROC TRANSPOSE and PROC REPORT. We would generate graph, using proc Gplot etc.

How Many Tables Can You Create In A Day?

Answer :

Actually it depends on the complexity of the tables if there are same type of tables then, we can create 1-2-3 tables in a day.

How Would You Submit The Docs To Fda? Who Will Submit The Docs?

Answer :

can submit the docs to FDA by e-submission. Docs can be submitted to FDA using Define.pdf or define.Xml formats. In this doc we have the documentation about macros and program and E-records also. Statistician or project manager will submit this doc to FDA.

What Are The Docs Do You Submit To Fda?

Answer :

We submit ISS and ISE documents to FDA.

Can U Share Your Cdisc Experience? What Version Of Cdisc Sdtm Have You Used?

Answer :

I have used version 3.1.1 of the CDISC SDTM.

Tell Me The Importance Of The Sap?

Answer :

This document contains detailed information regarding study objectives and statistical methods to aid in the production of the Clinical Study Report (CSR) including summary tables, figures, and subject data listings for Protocol. This document also contains documentation of the program variables and algorithms that will be used to generate summary statistics and statistical analysis.

Tell Me About Your Project Group? To Whom You Would Report/contact?

Answer :

My project group consisting of six members, a project manager, two statisticians, lead programmer and two programmers.

I usually report to the lead programmer. If I have any problem regarding the programming I would contact the lead programmer.

If I have any doubt in values of variables in raw dataset I would contact the statistician. For example the dataset related to the menopause symptoms in women, if the variable sex having the values like F, M. I would consider it as wrong; in that type of situations I would contact the statistician.

Explain Sas Documentation?

Answer : SAS documentation includes programmer header, comments, titles, footnotes etc. Whatever we type in the program for making the program easily readable, easily understandable are in called as SAS documentation.

How Would You Know Whether The Program Has Been Modified Or Not?

Answer : I would know the program has been modified or not by seeing the modification history in the program header.

What Is Project Status Meeting?

Answer : It is a planetary meeting of all the project managers to discuss about the present Status of the project in hand and discuss new ideas and options in improving the Way it is presently being performed.

Describe Clin-trial Data Base And Oracle Clinical?

Answer : Clintrial, the market's leading Clinical Data Management System (CDMS).Oracle Clinical or OC is a database management system designed by Oracle to provide data management, data entry and data validation functionalities to Clinical Trials process.18. Tell me about MEDRA and what version of MEDRA did you use in your project?Medical dictionary of regulatory activities.

Describe Sdtm?

Answer : CDISC’s Study Data Tabulation Model (SDTM) has been developed to standardize what is submitted to the FDA.

What Is Crt?

Answer : Case Report Tabulation, Whenever a pharmaceutical company is submitting an NDA, conpany has to send the CRT's to the FDA.

What Is Annotated Crf?

Answer : Annotated CRF is a CRF(Case report form) in which variable names are written next the spaces provided to the investigator. Annotated CRF serves as a link between the raw data and the questions on the CRF. It is a valuable toll for the programmers and statisticians.

What Do You Know About 21crf Part 11?

Answer : Title 21 CFR Part 11 of the Code of Federal Regulations deals with the FDA guidelines on electronic records and electronic signatures in the United States. Part 11, as it is commonly called, defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records.

What Are The Contents Of Ae Dataset? What Is Its Purpose?

Answer : What are the variables in adverse event datasets?

The adverse event data set contains the SUBJID, body system of the event, the preferred term for the event, event severity.

The purpose of the AE dataset is to give a summary of the adverse event for all the patients in the treatment arms to aid in the inferential safety analysis of the drug.

What Are The Contents Of Lab Data? What Is The Purpose Of Data Set?

Answer : The lab data set contains the SUBJID, week number, and category of lab test, standard units, low normal and high range of the values. The purpose of the lab data set is to obtain the difference in the values of key variables after the administration of drug.

Have You Created Transport Files?

Answer : Yes, I have created SAS Xport transport files using Proc Copy and data step for the FDA submissions. These are version 5 files. we use the libname engine and the Proc Copy procedure, One dataset in each xport transport format file. For version 5: labels no longer than 40 bytes, variable names 8 bytes, character variables width to 200 bytes. If we violate these constraints your copy procedure may terminate with constraints, because SAS xport format is in compliance with SAS 5 datasets.

```
Libname sdtm “c:sdtm_data”;Libname dm xport “c:dm.xpt”;
Proc copy;
In = sdtm;
Out = dm;
Select dm;
Run;
```

Have You Ever Done Any Edit Check Programs In Your Project, If You Have, Tell Me What Do You Know About Edit Check Programs?

Answer : Yes I have done edit check programs .Edit check programs – Data validation.

1.Data Validation – proc means, proc univariate, proc freq.Data Cleaning – finding errors.

2.Checking for invalid character values.Proc freq data = patients;Tables gender dx ae / nocum nopercent;Run;Which gives frequency counts of unique character values.

3.Proc print with where statement to list invalid data values.[systolic blood pressure - 80 to 100][diastolic blood pressure – 60 to 120]

4.Proc means, univariate and tabulate to look for outliers.Proc means – min, max, n and mean.Proc univariate – five highest and lowest values[stem leaf plots and box plots]

5.PROC FORMAT – range checking

6.Data Analysis – set, merge, update, keep, drop in data step.

7.Create datasets – PROC IMPORT and data step from flat files.

1.Extract data – LIBNAME.

2.SAS/STAT – PROC ANOVA, PROC REG.

3.Duplicate Data – PROC SORT Nodupkey or NoduplicateNodupkey – only checks for duplicates in BYNoduplicate – checks entire observation (matches all variables)For getting duplicate observations first sort BY nodupkey and merge it back to the original dataset and keep only records in original and sorted.

4.For creating analysis datasets from the raw data sets I used the PROC FORMAT, and rename and length statements to make changes and finally make a analysis data set.

What Is Verification?

Answer :

The purpose of the verification is to ensure the accuracy of the final tables and the quality of SAS programs that generated the final tables. According to the instructions SOP and the SAP I selected the subset of the final summary tables for verification.

Example: Adverse event table, baseline and demographic characteristics table.The verification results were verified against with the original final tables and all discrepancies if existed were documented.

What Is Program Validation?

Answer :

Its same as macro validation except here we have to validate the programs i.e according to the SOP I had to first determine what the program is supposed to do, see if they work as they are supposed to work and create a validation document mentioning if the program works properly and set the status as pass or fail.Pass the input parameters to the program and check the log for errors.

What Do You Lknow About Iss And Ise, Have You Ever Produced These Reports?

Answer :

ISS (Integrated summary of safety):Integrates safety information from all sources (animal, clinical pharmacology, controlled and uncontrolled studies, epidemiologic data). "ISS is, in part, simply a summation of data from individual studies and, in part, a new analysis that goes beyond what can be done with individual studies."ISE (Integrated Summary of efficacy)ISS & ISE are critical components of the safety and effectiveness submission and expected to be submitted in the application in accordance with regulation. FDA’s guidance Format and Content of Clinical and Statistical Sections of Application gives advice on how to construct these summaries. Note that, despite the name, these are integrated analyses of all relevant data, not summaries.

Can You List The Variables In All The Domains?

Answer :

1.Demog: Usubjid, Patient Id, Age, Sex, Race, Screening Weight, Screening Height, BMI etc

2.Adverse Events: Protocol no, Investigator no, Patient Id, Preferred Term, Investigator Term, (Abdominal dis, Freq urination, headache, dizziness, hand-food syndrome, rash, Leukopenia, Neutropenia) Severity, Seriousness (y/n), Seriousness Type (death, life threatening, permanently disabling), Visit number, Start time, Stop time, Related to study drug?

3.Vitals: Subject number, Study date, Procedure time, Sitting blood pressure, Sitting Cardiac Rate, Visit number, Change from baseline, Dose of treatment at time of vital sign, Abnormal (yes/no), BMI, Systolic blood pressure, Diastolic blood pressure.

4.ECG: Subject no, Study Date, Study Time, Visit no, PR interval (msec), QRS duration (msec), QT interval (msec), QTc interval (msec), Ventricular Rate (bpm), Change from baseline, Abnormal.

5.Labs: Subject no, Study day, Lab parameter (Lparm), lab units, ULN (upper limit of normal), LLN (lower limit of normal), visit number, change from baseline, Greater than ULN (yes/no), lab related serious adverse event (yes/no).Medical History: Medical Condition, Date of Diagnosis (yes/no), Years of onset or occurrence, Past condition (yes/no), Current condition (yes/no).

6.PhysicalExam: Subject no, Exam date, Exam time, Visit number, Reason for exam, Body system, Abnormal (yes/no), Findings, Change from baseline (improvement, worsening, no change), Comments

What Do You Feel About Hardcoding?

Answer : Programmers sometime hardcode when they need to produce report in urgent. But it is always better to avoid hardcoding, as it overrides the database controls in clinical data management. Data often change in a trial over time, and the hardcode that is written today may not be valid in the future.Unfortunately, a hardcode may be forgotten and left in the SAS program, and that can lead to an incorrect database change.

How Do You Write A Test Plan?

Answer :

Before writing "Test plan" you have to look into on "Functional specifications". Functional specifications itself depends on "Requirements", so one should have clear understanding of requirements and functional specifications to write a test plan.

What Is Locf?

Answer :

Pharmaceutical companies conduct longitudinalstudies on human subjects that often span several months.

It is unrealistic to expect patients to keep every scheduled visit over such a long period of time.Despite every effort, patient data are not collected for some time points. Eventually, these become missing values in a SAS data set later. For reporting purposes,the most recent previously available value is substituted for each missing visit. This is called the Last Observation Carried Forward (LOCF).LOCF doesn't mean last SAS dataset observation carried forward. It means last non-missing value carried forward. It is the values of individual measures that are the "observations" in this case. And if you have multiple variables containing these values then they will be carried forward independently.

Who Sponsors Clinical Trials?

Answer : Clinical trials are sponsored or funded by a variety of organizations or individuals such as physicians, medical institutions, foundations, voluntary groups, and pharmaceutical companies, in addition to federal agencies such as the National Institutes of Health (NIH), the Department of Defense (DOD), and the Department of Veteran's Affairs (VA). Trials can take place in a variety of locations, such as hospitals, universities, doctors' offices, or community clinics.

What Are All The Procs Have You Used In Your Experience?

Answer : I have used many procedures like proc report, proc sort, proc format etc. I have used proc report to generate the list report, in this procedure I have used subjid as order variable and trt_grp, sbd, dbd as display variables.

Describe The Data Sets You Have Come Across In Your Life?

Answer : I have worked with demographic, adverse event , laboratory, analysis and other data sets.

How Did You Do Data Cleaning? How Do You Change The Values In The Data On Your Own?

Answer :

I used proc freq and proc univariate to find the discrepancies in the data, which I reported to my manager.

Have You Created Crt's, If You Have, Tell Me What Have You Done In That?

Answer :

Yes I have created patient profile tabulations as the request of my manager and and the statistician. I have used PROC CONTENTS and PROC SQL to create simple patient listing which had all information of a particular patient including age, sex, race etc.

Explain Types Of Clinical Trials Study You Come Across?

Answer :

Single Blind Study:

When the patients are not aware of which treatment they receive.

Double Blind Study:

When the patients and the investigator are unaware of the treatment group assigned.

Triple Blind Study:

Triple blind study is when patients, investigator, and the project team are unaware of the treatments administered.

What Are The Domains/datasets You Have Used In Your Studies?

Answer :

- ✓ Demog
- ✓ Adverse Events
- ✓ Vitals
- ✓ ECG
- ✓ Labs
- ✓ Medical History
- ✓ PhysicalExam etc

What Is The Difference Between Verification And Validation?

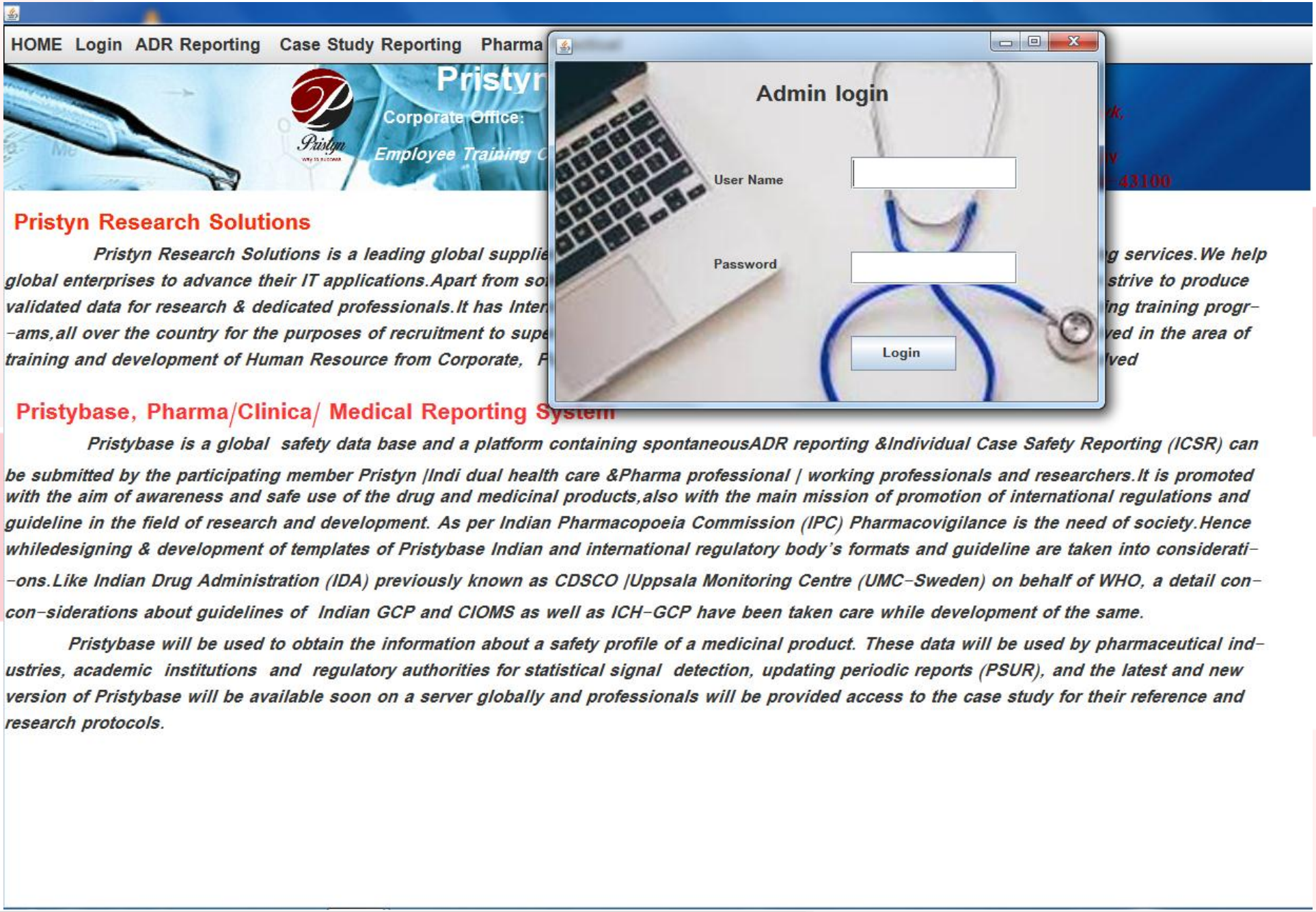
Answer :

Although the verification and validation are close in meaning, "verification" has more of a sense of testing the truth or accuracy of a statement by examining evidence or conducting experiments, while "validate" has more of a sense of declaring a statement to be true and marking it with an indication of official sanction.

What Other Sas Features Do You Use For Error Trapping And Data Validation?

Answer :

- ✓ Conditional statements, if then else.
- ✓ Put statement
- ✓ Debug option.



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Pristyn Research Solutions is a leading global supplie ...g services.We help global enterprises to advance their IT applications.Apart from so... strive to produce validated data for research & dedicated professionals.It has Inter... ...ing training progr--ams,all over the country for the purposes of recruitment to supe... ...ved in the area of training and development of Human Resource from Corporate, P... ...lved

Pristybase, Pharma/Clinica/ Medical Reporting System

Pristybase is a global safety data base and a platform containing spontaneousADR reporting &Individual Case Safety Reporting (ICSR) can be submitted by the participating member Pristyn |Indi dual health care &Pharma professional | working professionals and researchers.It is promoted with the aim of awareness and safe use of the drug and medicinal products,also with the main mission of promotion of international regulations and guideline in the field of research and development. As per Indian Pharmacopoeia Commission (IPC) Pharmacovigilance is the need of society.Hence whiledesigning & development of templates of Pristybase Indian and international regulatory body's formats and guideline are taken into considerati--ons.Like Indian Drug Administration (IDA) previously known as CDSCO |Uppsala Monitoring Centre (UMC-Sweden) on behalf of WHO, a detail con-con-siderations about guidelines of Indian GCP and CIOMS as well as ICH-GCP have been taken care while development of the same.

Pristybase will be used to obtain the information about a safety profile of a medicinal product. These data will be used by pharmaceutical ind--ustries, academic institutions and regulatory authorities for statistical signal detection, updating periodic reports (PSUR), and the latest and new version of Pristybase will be available soon on a server globally and professionals will be provided access to the case study for their reference and research protocols.

C. SUSPECTED MEDICATION(S)

Report Number
Sr.No
8. Name (Brand/Generic)
Manufacturer (if known)
Batch No. / Lot No.
Exp. Date
Dose used
Route used
Frequency (OD, BD etc.)
Therapy dates strated
Therapy dates stopped
Indication
Causality Assessment
Add

Report Number	S.No	8. Name (Bran...	Manufacturer (...	Batch No. / Lot...	Exp. Date (if k...	Dose used	Route used	Frequency (O...	Therapy dates...	Therapy dates...	Indication	Causality Ass...

9. Action Taken(in Yes or No)

Report Number
S.No as per C: 1
Drug withdrawn: YES
Dose increased: YES
Dose reduced: YES
Dose not changed: YES
Not applicable: YES
Unknown: YES

10. Reaction reappeared after reintroduction (please tick): YES

Effect unknown: YES
Dose (if reintroduced)
Add

Report Number	S.No as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Reaction reappe...	Effect unknown	Dose (if reintrodu...

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

Report Number
Sr.No
Name (Brand/Generic)
Route Used
Frequency (OD, BD, etc.)
Therapy dates started
Therapy dates stopped
Indication
Add

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Current Standard Hiring Process of Companies

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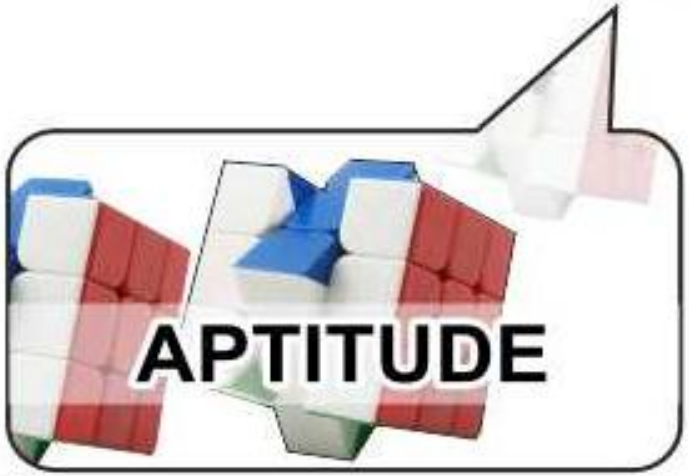

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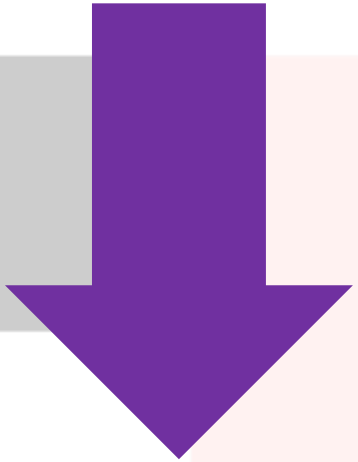

Check

Pharmacovigilance | Clinical Research | Clinical Data Management
Drug Regulatory Affairs | Pharma Q.A / Q.C | Pharma Production
Pharma Digital Marketing | R & D | Medical Coding
Medical Transcription | Medical Writing | Research Publications

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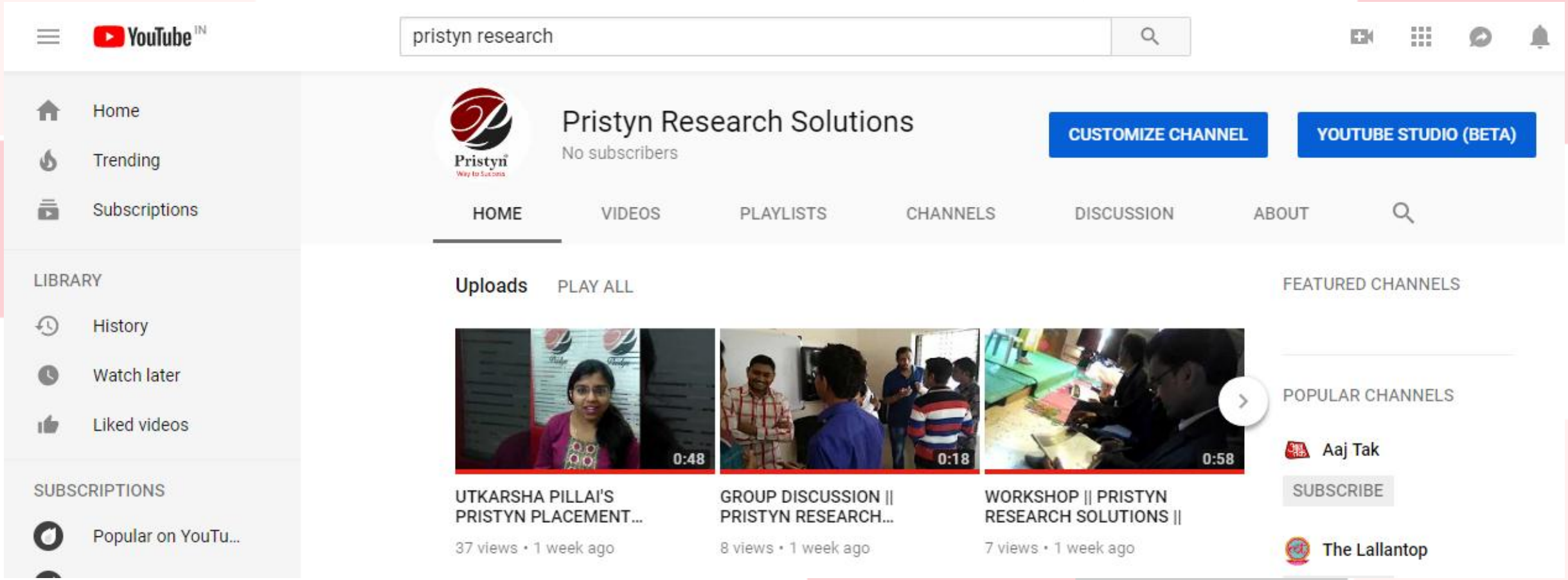

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STUDENT SPEAK ABOUT PRISTYN TRAINING & PLACEMENT PROGRAM

"If you have joined Pristyn, your career and you, both are in good hands! Pristyn had a solution for every problem of mine. Joining here was the best decision. After coming here, I came to know what it takes being the best and stand out from the rest. Pristyn helped me to challenge any interview with my training and technical knowledge."
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LAST

Malviya proposed a vote of thanks.

Shivaji College of Pharmacy, Deori

Guests present at the workshop.

A DAYLONG workshop on "Students Industrial Pre-Placement Programme" was organised by Chhatrapati Shivaji College of Pharmacy, Deori in association with MSBTE, Mumbai and Pristyn Research Solution ,Pune. The main objectivebehind organising the workshop is to create awareness among the student about the industrial demand for skilled manpower to have employability. Pristyn Director Pathan Azhar Khan guided on Drug Discovery to Approval process with latest requirements and international regulations. The delegates were acquainted with role and responsibilities, interview techniques and job requirement . Pristyn Counselor Pavitra Shibad and Vinod Nair explains about the importance of having pleasant personality, soft skills and communication skills. In this workshop, Zhamsing B. Yerne, President Krushna Sahypgi Tantra Shikshan Sanstha (Deori) Presided over while Dr. Milind Umekar ,Principal SKB College of Pharmacy, Kamptee and Dr. Dinesh Biyani Associate Prof. were chiefly present alongwith Anil Z. Yerne ,Secretary and Jayshree Yerne. Dr Milind Umekar also spoke on the occasion.Earlier, Upadesh Bhimrao Lade, Principal of Chhatrapati Shivaji College of Pharmacy, Deori delivered inaugural speech. Meenakshi Mhaske conducted the proceedings while Co-ordinator Sandipkumar Agrawal proposed vote of thanks.

Shri Shivaji College, Akola

About Pristyn Research Solutions:

Pristyn Research Solutions is a leading global supplier of I.T, Clinical, Pharmaceutical services and Knowledge processing services. We help global enterprises to advance their IT applications. Apart from software developments and frame-work global services Pristyn provide corporate training in profession and skills development. We strive to produce validated data for research & dedicated professionals. It has International affiliations and regional government approvals for organizing training programs, all over the country - for the purposes of recruitment to superior posts. It has huge associations of individuals and group involved in the area of training and development of Human Resource from Corporate, Public, Private Sector Organization & other Professional Bodies.

For us every candidate is important & every company is unique. This is a place where a candidate identifies his/he career loopholes, overcome those & match the principle of RIGHT CANDIDATE FOR RIGHT JOB.

Short-Term Industrial & Corporate Training on: (Life-Science)

(A) Domain	(B) Domain	(C) Domain
1. Clinical Research	1. Pharma Q.A/Q.C	1) Medical Coding
2. Pharmacovigilance	2. Pharma Production	2) Medical Writing |MS
3. Clinical data Management	3. DRA | Ph-Digital Marketing	3) P.V| Research Publications
4. Drug Regulatory Affairs	4. R & D	4) DRA
Duration= 3 Months	Duration= 3 Months	Duration= 3 Months

28 Days Job Training

- Technical Terminologies used in Interviews and Job Workplace.
- H.R and Company Communication Skills
- Mock Interviews and Professionalism
- Aptitude Training and Brain Boosting
- Group Discussion and Teamwork
- Job Search/Job Applying Tools and Tricks
- Computer & Online literacy required for Job
- Job and companies Applications /Email Writing
- Resume/C.V and Profile Building
- Motivational Lectures by industry Persons
- Career Guidance/ Self-Confidence Boosting
- Brush up-on English language.
- Soft Skills and communication
- Personality Development & Presentation Skills
- Placement Tools and Assistance
- Other Customize and personal Support

Advanced PGD & Professional Internship Program (Life-Science)

(Drug Discovery to Approval)

All Domains

Duration= 4+ 2 Months

2 Months Project & Placement

Short-Term Industrial & Corporate Training on: (I.T)

Domain	Domain	Duration=3 M
1. JAVA	1. .NET	Live Client Project and
2. PHP	2. PYTHON	Development Work for 1 Month

Advanced PGD & Professional Internship Programed (I.T)

Domain	Domain	Duration= 6 Months
1. JAVA	1. .NET	Live Client Project and
2. PHP	2. PYTHON	Development Work for 2 Month

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