WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 9, Issue 8, 991-1031. Review Article ISSN 2277– 7105

REPORT ON THE STUDY OF NOVEL APPROACHES, TECHNICAL CONSIDERATION AND SUPPORT IN THE TREATMENT THERAPY AND PANDEMIC INFECTION PREPAREDNESS FOR THE RECENT EPIDEMIC OUTBREAK OF SARS-CoV-2 INFECTION, COVID-19 DISEASE AND PANDEMIC MANAGEMENT INCLUDING CLINICAL TRIALS SOLUTIONS AND REQUIRED DOCUMENTATION PROCEDURES

Saurabh Dilip Bhandare*

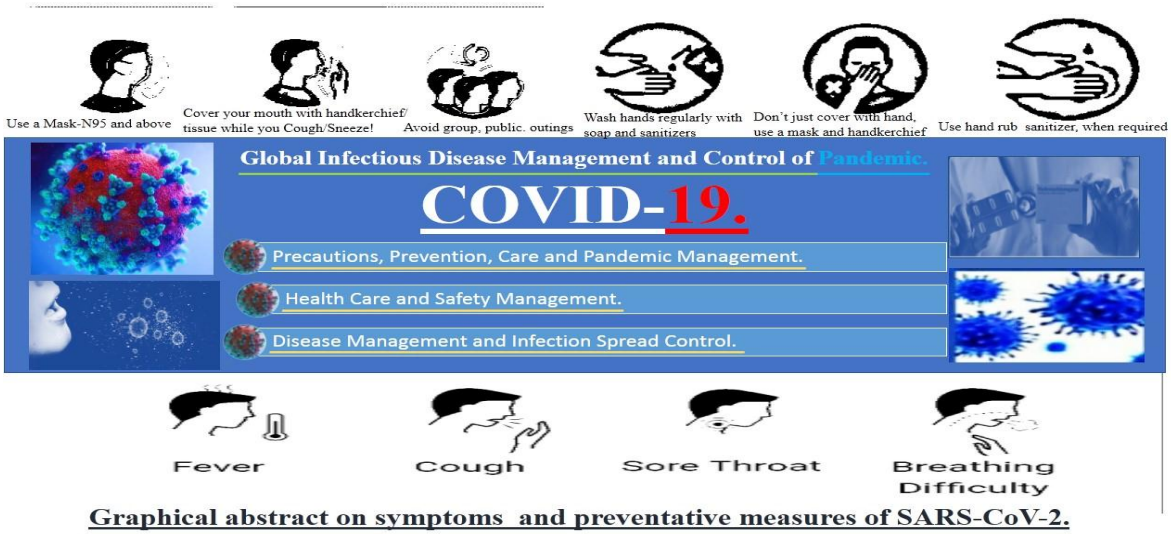
MET'S Institute of Pharmacy, Bhujbal Knowledge City, Adgaon, Nashik, Maharashtra, India. 422003. Affiliated to SPPU, Pune.

Article Received on
10 June 2020
Revised on 30 June 2020
Accepted on 20 July 2020
DOI: 10.20959/wjpr20208-18218

***Corresponding Author**
Saurabh Dilip Bhandare
MET'S Institute of Pharmacy, Bhujbal Knowledge City, Adgaon, Nashik, Maharashtra, India. 422003. Affiliated to SPPU, Pune.

ABSTRACT

In this recent outbreak of an epidemic infection-COVID-19 caused by SARS-CoV-2, which led to have caused pandemic that had begun in the years (December 2019), 2019. First it had started or it had emerged into the city of Wuhan and then in a time period had spread rapidly throughout the China. In the early December; 2019, the first case of pneumonia was observed from an unknown origin and was identified to be emerged in the city of Wuhan, the capital city of Hubei province; in the China. The pathogen was identified to be as a novel enveloped RNA beta corona virus, that is SARS-CoV-2, which had caused varying degrees of illness in patients; those are: often found to be diagnosed with symptoms such as: conjunction, congestion, nasal congestion, headache, cough, sore throat, sputum production, fatigue, haemoptysis, shortness of breath, nausea or vomiting, diarrhoea, myalgia or arthralgia, chills etc. that is caused by the infection of COVID-19-SARS-CoV-2 a disease causing agent or pathogen, which is a mammalian virus, termed SARS/MERS- Severe acute respiratory syndrome, middle east respiratory syndrome; are zoonotic. The term novel corona virus is most significant in the recent study practices about the pandemic/pandemics. (nCoV).



Graphical abstract on symptoms and preventative measures of SARS-CoV-2.

KEYWORDS: SARS-CoV-2-COVID-19-Pandemic or epidemic, U.S.FDA, U.K.MHRA, Emergency medication-primary care, viral infection and global health-pandemic preparedness.

1. INTRODUCTION

The novel corona virus (nCoV) emerged in the China in late 2019; it had been officially named by the world health organization (WHO) as COVID-19. The world had already been affected with the effects of epidemics that is caused by SARS-CoV-2, a virus leading to had cause infection of COVID-19 in the vast population in human across various countries around the globe. The virus is a member of the coronavirus family and is zoonotic, or transmissible from animal to humans and is thought to have originated in bats, but however this is not yet evident and clear as bats can cause infection of Ebola, than infection of Corona.

Researchers are working hard and definite in the field to develop therapeutics for the treatment of its infection that is caused by virus, SARS-CoV-2. Epidemiological and laboratory studies demonstrated that viral load is highest found early in illness and before symptoms onset, that viral particles could remain infected with the virus contributing transmission of infection. This had led to a situation of global health crises leading to a pandemic causing an exigent situation on earth. The spread of SARS across the globe had occurred in a quarter period of time, then after its first case noted in the city of Wuhan in early December 2019 and then after in the China and various countries around the globe. This had affected a large population in various countries, who had been open exposed or faced with the infection or had got infected over the time from person to person; which had led to tremendous loss in human population and had been a rapid attacking disease noted ever in the

human history. The scientific community along with the HCP's had faced an ordeal dealing with this new virus attack in human population which was uncontrollable and thus had to be taken into an exigent state in human leading to cause a pandemic. Such ordeal had been faced and managed by the HCP's for numerous reasons; one such was: 'lack of the information on novel Corona Virus (nCoV), SARS-CoV-2 and its origin in humans. In later studies, detailed scientific and HCP's investigations have been confirmed and been made to declare it as a human SARS-CoV-2 virus that causes Severe Acute Respiratory Syndrome in humans as well the virus is zoonotic.

To this already faced challenges and ordeal due to lack of knowledge on new virus, available data resources such as sufficient information and scientific details available and the most significant is that unavailability of medications. Lack of preparation of sufficient details of infection in the early stage of the pandemic.

1.1. Comparison of fatality rate or (case fatality ratio), for both cases of similar types of viruses that is SARS and MERS are

The Corona virus case fatality rate or ratio had been estimated at around 2% in the initial stage as per WHO. (January 29, 2020).

For comparison between SARS and MERS: Case fatality ratio/rate SARS and MERS is 10% to 34% respectively.

1.2. Matter of Concerns involved in safe-guarding human population during the entire time period of pandemic caused by SARS-CoV-2 and then after, includes

1) Public safety, **2)** Public health care and issues, **3)** Addressing healthcare issues and facility requirements, **4)** Support to establish standards in concerned area of interests, **5)** Support to establish well documented reports producing sufficient details on pandemic and human responses and conditions in the humans. **6)** Special concerns involved in travelling through public transports or private transport or any other ways of either services to commute where large public is involve

Figure: 1. Hygiene practices carried during the SARS-CoV-2 pandemic at the time of travel/ commute.

7) Special safety issuance on the forum of public health safety and wellbeing. **8)** Well responsive evaluation of the respective concerned fatalities required during the time of an outbreak of epidemic. **9)** Sufficient issuance of guidance and concerns addressed through the media in fulfilment of the demand to meet the human health safety issues and concerns involved during every stages of pandemic. **10)** Involvement of various plans that outlines human's safety throughout the time period in the issuance of public health care systems. **11)** Establishment of various plans to safeguard human population of a varying regions throughout the geographies across various countries around the globe. Various sets of population which should involve/include all sets of population, fare in terms and non-discriminated on any of the regional background of the region, place or a country, including such as: origin, nationality, colour, race, ethnicity, sex, people with varying disabilities, geriatric population, neonatal population, sexual orientation, age and any of the status-married or unmarried, individual abilities, relationship status etc. In particular preparation of safety plans, including HRPs, RRPs, RMRP plans etc.

1.3. SARS-CoV-2 transmission and affect

i) Snippet: There are strong evidences that SARS-CoV-2 can be transmitted by the people who are just mildly ill or are even pre-symptomatic. That means COVID-19 will be having

more of the reproductive number. For comparison, the R_0 for the common flu is 1.3 and for SARS-CoV-2 it was 2.0 which was noted at the initial stage of the pandemic. If the outbreak with the number below **1, < 1** should be gradually eliminated/disappear. Although in the condition of flu which can be treated with the help of proper medications.

1.4. Serology tests: (Serologic tests)

Application of serology in diagnosis of infection in human involves/ includes: responsible laboratories for conducting tests use rapid detection kits that detects antibodies or antigen of the particular virus in the sample at the earliest and easiest: e.g. Perkin Elmer new corona virus nucleic acid detection kit. Serologic diagnosis.

The nucleo-capsid protein based Immunoglobulin-G ELISA techniques gives or shows better results to detect the SARS-CoV-2. Apart from these tests, neutralization test or immuno-fluorescent assay serve as alternate ways of detection.

1.5. Conduct of clinical research

Available details found on research study, experts to conduct clinical research in Russia which includes: **i)** Established patients funnels, **ii)** Competitive private clinics, **iii)** Research accredited sites, **iv)** Favourable cost structure. This includes the global business of development of small molecules on therapeutics issuance in issuance to safeguard the health care systems and build the safety in human and animal population.

Figure: 2. GCP and GLP as a best practice to safeguard patient's life.

1.6. Clearance of terms and terminologies in the pharmaceuticals

i) Drug: This includes a pharmaceutical drug/ pharmaceutical entity/ a licenced therapeutic products/or an I.P., I.M.P's.

1.7. Best documentation practices that are required to be maintained throughout the evaluation procedures

The best documentation practices that are required to be maintained throughout the evaluation procedures includes, GDP: Good documentation practices.

1) Request in demand of a issuance of guidance, particularly from the local and or the national government, ethics in particulars to avoid or stop expressing; excessive or any interest in producing any materials which includes but is not limited to expressions of hatred or expression or showing jingoism that can lead to cause disturbance in safety of people or will affect the trust of people in a refugee where lots of different population is involved. **2)** Survival safety and infection prevention and control plans issued in the public health care safety practices/operation to the public health care sectors made in such to control of any post occurrence of pandemic states in humans. **3)** Plans to help established government recognised, hygienic food facilities in issuance and vending of food in the time of pandemic or epidemic that is well controlled and prepared with hygienic practices. **4)** Include a document to be kept ready i.e. documents readiness in response to handle of such cases of a certain outbreak that can cause pandemic or epidemic, which also includes the new disease occurrence. This should include: data and information for various population sources including every aspects of a human health care systems and also the veterinary health care systems. Well documentation of such occurrence of epidemic such in which includes training forms, subjects, trainer, training materials, available medications, impacts of human health and animal health. Further laboratory studies of such viruses which can affect the earth through various sources and about its all possible genetic mutants to safe guard both human and animal population across the globe. **5)** Quarantine, of the affected population and inclusion of all the possible available treatment to safeguard the patients and its wellbeing. Inclusion of regular health check-ups for the survived/ recovered population to find if any possible re-emerging of infection or any degree of health issues that could be noted at the time. **6)** Allowance of inclusion of newly developed medication under the National Healthcare System of every country. Such registration should be made and recorded in terms of documents submission to the regulatory agencies, regulatory bodies of the particular countries. One such agency is U.S.FDA. **7)** Local, national and international register of any newly developed therapeutic that should promise to combat the pandemic without any side-effects should be made into register; such as: **a)** newly developed chemical entity, chemical intermediates. **b)** Salts of already developed medication which can prove to be beneficial. **c)** Biological molecules. **d)** Reported incidence with or if any with the inert materials such as:

Polymers. **8)** Registry of any reported incidences that includes any drug interactions: **i)** Drug+Drug, **ii)** Drug+Food, **iii)** Drug+Condition. **9)** Extensive study in the field of newly developed medication safety and its evaluation in terms of: **i)** Safety, **ii)** Efficacy, **iii)** Bio-availability, **iv)** Study of first pass effects of new drugs. **v)** Metabolism and elimination, **vi)** Toxicity, **vii)** Fixed dose combination. etc. **10)** Inclusion of medical and regulatory specialists to oversee and guide on critical requirements on end to end deliverables which help manufacturers to summarize safety/vigilance and to maintain product complaint data of a post-marketed medicines or healthcare products on a healthcare devices or medical devices which is gradually/significantly less in the well-established, well developed and processed products from reputed pharmaceutical manufacturing companies and healthcare sectors. **11)** Allowance of generic drug materials in special cases if required under any special condition and permission obtained from the manufacturer to seek a grant or licence to develop genetic materials or to see if the licensed or patented products of the company is available for generic production. **12)** Focused on bringing of over-the-counter (OTC) drug or medication to market if any immediate requirement. Also includes purpose to provide information/information on bringing an OTC drugs to market and the associated FDA process as chemistry manufacturing and control (CMC) perspective of the IND. **13)** Emerging with FDA during New Drug Development: This includes process to follow on and focuses on familiarizing small pharmaceutical business and industries in general with available resources to communicate with FDA and provide guidance on effectively interacting with FDA, throughout the new drug development process. The process for evaluating and approving drugs can go awry or out of kilter during a public health crisis. This also includes pandemic disease drug development plan under global drug development plan under global drug development (GDD) for its registry on the effective development in the field of therapeutics of both human and animals that is inclusive of proper healthcare solutions to humankind. This is also subjected to include human drug establishment registration and drug listing compliance that identifies and produces the statutory requirements regarding the submission of registration and drug listing information and provides a clearer understanding of the registration and drug listing process. This also includes a virtual trials in case of pandemic where in a quarantine of the caused disease in required virtual trials includes bringing trials directly to patients to decrease costs, increase quality and improve access to medicines/medical, healthcare facilities and increase the chance of human survival safety. This also includes provision of preserving privacy of human subjects under trial with the required rules and regulations and subjective disclosure on requirements/produce in which

any documents is required by the local ethics committee, under any matter of concerns. **14)** Enabling a platform/interface to discuss a faster more flexible, convenient and less expensive approaches for scientific enquiry into human biology, drug discovery and drug development that includes systems that have capacity to capture and store human data, human data sciences in systems such as: HIT. This enmarks (register) the problems and resolve the challenges in human health and realize the potential of big data in healthcare and research development of therapeutics and pharmaceuticals, healthcare systems. This also helps in command of the country level parameter to perform according to the required local or international standards as applicable, that is applicable to the local and international standards as applicable in accordance to the local and international regulations and standard operating procedures (SOP's) in a manufacturing company and HIT as per the manufacturing requirements of the pharmaceutical products and the guidelines. This also includes documentation of manufacturing onsite activities and record maintenance. Such as data on audits, quality reports such as: BMR, IPQC, records on testing procedures and GMP and GLP records on a manufacturing site which is under general supervision or in records kept with the manufacturing company or the manufacturer or with the Q.C. head In-charge of the company or the department of a manufacturing company and laboratory In-charge. This includes documentation of the healthcare systems which works on HIT; Such as: A CRO based organization of a parent research organization that works and conducts in accordance of required standard practices which ensures adherence to standard operating procedures (SOPs), following of work instructions (WIS), quality of designated deliverables and in process submission to meet the urgent requirements of quality deliverables in the subjected project timelines. This also ensures the study to perform regulatory tasks that includes quality submission of case studies, eCTDs, INDs, filling of ANDA, original submissions, amendments etc. which includes regulatory and maintenance activities according to applicable regulations, SOP's and work instructions which also includes distribution/submission of completed documentation that are necessary to manufacture at sites and maintain internal standards. Inclusion and preparation of document readiness for preparing of site regulatory documents, which includes a onetime submission as a fresh document which is not amended or unamended **(fresh-submission)** and that if required will be needed to amend or as per requirement which only includes changes in some parameters such as: **a)** missing data to be resubmitted and filled. Amendments including major changes that should be well documented and communicated at the respected levels of significant responsible bodies. Such submission never includes audit data but the data/documents should

be filled and maintained for special internal requirements for internal inspection or external inspections.

15. Such document preparation/preparedness includes:

A.) Prepare manufacturing site regulatory documents, reviewing for its completeness and accuracy.

B.) Review, prepare and maintain applicable manufacturing site data. Well documented details on information available from external sources such as journal data from a scientific journals.

C.) Maintenance of the budget reports that are with the manufacturers.

D.) Ensure accurate completion and maintenance of internal filing systems for document maintenance, this also includes free and easy user interface as a more complex and complicated user interface makes it difficult data in time and process it at the easiest and writhing the required time. Any time consuming procedures should be optimised. Thus such systems should be user friendly well suited to be used by humans and should be of at a glance and should have no hidden prospective. (User friendly interface.).

E.) Review and provide feedback to manufacture site and the responsible authorities on varying details. This includes patient monitoring details, patients materials, implementing contingency plans as and when needed.

F.) Information on completion of regulatory and contractual documents for individual responses and audit report preparedness etc. Documents also includes: approval documents with the approval dates, contracts details of HCP and P.I. of the projects, regulatory submission documents, including amendments, documents on ethics and ethics committee, inclusion, customization, review of ICF before submission, release details of I.P. i.e. I.P. release documents fully signed and well documented and are duly signed when required by the P.I. and S.N. which is in line with the projects.

G.) Provide an expertise review in the timelines to the initial submission of the documents which includes: ANDA, IND, filing etc. This also includes the procedure to perform quality control of documents that are provided by the manufacturing sites in pharmaceutical, or in a clinical research, investigation site along with the P.I. that may have direct contact with sponsors on specific initiatives. This requires knowledge, skills, abilities and guidance to the subject along with proper training to the HIT resources which also includes in-depth knowledge and documentation processes which are required to be prioritize at the time of emergencies. Emergencies such as one faced recently: COVID-19 pandemic. This also

includes processing of documents and guidance accordance to the ICH-GCP and as per the applicable regulatory guidelines.

H.) Involvement and recruitment of proper healthcare providers at the site and also at manufacturing units for/during the entire time. (At the time of pandemics.), and epidemics is much necessary to combat the risk of safety and avoided frauds or duplicates that can affect the health care systems.

I.) Making of positive impacts on human health care systems is very important in dealing with the time of emergencies and taking critical decisions.

J.) Patenting of intellectual materials of significant importance is a must parameter to safe guard the intellectual property of a person or a manufacturer of this which also includes copyright on logos, trademarks, and designs which are included in stamps and seals of the company or organization, provided that it is truly and genuinely produced and hold a matter of prime criteria of patenting and copyrighting of a particular subject matters.

K.) Improvement in the quality of outputs and receiving of inputs together in handling of health care systems in a safe health driven environment to practice and perform a safe and improved outcome for patient's safety and wellbeing.

L.) This includes proper, clinical task handler which includes HCP's, some of the key roles at the site which includes P.I., S.N. etc. While in conducting trials at the study site.

M.) Before initiating trials, proper investigations of I.B. by the P.I., S.N., role on pharmacists and other healthcare professionals to agree in the study conductance and its safety after investigating the I.B.

N.) Proper study of sponsor specific details and study data is required at the time of initiating the study at the clinical site.

O.) Patients safety, is a must criteria and to be well documented in terms of study subject safety.

P.) Includement (including) of proper solutions to harness the right solution in the healthcare systems.

Q.) Collection, storage and maintenance of data well obtained in documented formats for further investigation of safety this includes:

i.) Pharmacological data i.e. efficacy, safety, bioavailability, side effects, any suicidal drug induced tendency, drug induced impairment and notable adverse events, notable behavioural changes and activities and responses. (change in behaviour observed in neuroleptics for long terms).

ii.) Toxicity.

R.) To investigate the proper maintenance of quality of clinical conduct by the P.I. in accordance with the I.B. and duly signed study reports and ensurement of the study conducted in accordance with the I.B. provided at the time of study and also proper ensuring of the study conducted is qualified, designed, verified and proper conduct of study according to study protocol that is in accordance to ICH-GCP and also ensurement of proper duly signed data collected at the time of study from the site. Properly signed documents includes: signed documents with the date.

Evaluating of all the necessary P.I. details who will conduct the study for the sponsored or the sponsoring company.

Making sure that all the necessary documents are duly signed and well documented at the time of study, signed and cross verified by the P.I. and S.N. at the time of study on same date and T.O.D.

Ensuring that the entire study is rolled over by the P.I. and should be completed under the P.I. observation and guidance. If any requirement to cancel the study in between or to their requirement to terminate the study conducted due to various reasons, then should must be conducted and terminate in observation made particularly in writing by the P.I. and such must be made in writing by the P.I. and with qualified and eligible site staff to perform such study under clinical investigations reports to be well documented.

R.i.) Include duly signed P.I. reports on the conducted study.

R.ii.) Special reports on any study failure or device failure.

R.iii.) Calibration details of all the functional devices available and to be used in the time of conductance of study.

R.iv.) Review of P.I. on safety of trial at the venue/P.I. qualified study site.

R.v.) Review of P.I. after investigating the I.B.

R.vi.) Review of P.I. for any possibilities of changes in the study.

R.vii.) Review of P.I. on any disqualification in the study.

R.viii.) Recruitment of HCP and their details throughout the time of the conducted study.

R.ix.) Review of P.I. on duly signed budgets of the proposement of the study.

R.x.) Review of P.I. on any disqualification on trial subjects.

R.xi.) Review and preparation of all the study documents including the safety data that is duly signed with a seal of the trial conducting facility/hospital/P.I. site.

R.xi.a.) Preparation of documents which include production of high-quality patient recruitment materials for site and patient network (SPN.).

R.xi.b.) Assessment in evaluation of documents for type setting and proofreading.

Identification of the errors in the SPN and making electronic corrections, by authorised personnel to the accessed details and submit in PDF format.

R.xi.c.) Checking of accuracy of the documents for the purpose of fulfilling the regulatory requirements and also requirements in managing the proof and amendments, to verify whether the amendments are implemented correctly on revised proofs and finalising clean files.

R.xi.d.) Assessment of software to generate proper print quality documents. Validating and implementing changes.

R.xi.e.) Documents describing accelerating the vaccines development process workflow, from discovery of the drugs to the production of formulation for patients administration.

R.xi.f) Documents signifying the use of drugs during COVID-19 pandemic with all possibilities as per the WHO and ICH documentation.

R.xi.g.) Documents indicating of any risk of usage of drugs during COVID-19 pandemic for example, chemotherapy may be needed to postpone as this can compromise the immune system and make the patients more vulnerable to developing COVID-19 disease. Making of such delay of therapy and noting of such information by the physician of respective patients in the patients case report form should be well documented with including the document of cause of concern.

R.xi.h.) Form 1572 of FDA to be included for the individual commitment of P.I.

R.xi.i.) Verifying raw material for drugs manufacturing and preventing FDA warning letters. These includes documents on: analysis of incoming excipient and active pharmaceutical ingredients (APIs), is a crucial aspect of a pharmaceutical Q.A. /Q.C. laboratory.

R.xi.j.) GMP quality compliance: The good and the bad aspect of quality and improvements. This includes whitepaper discussion on how to establish effective audits with fully articulated Q.A. /Q.C. programs (the good), and will keep the bad out of GMP quality compliance. This also includes documentation on quality control and generic drug production. Generic drug share the same essential qualities of that branded product, however may vary in production and use of design for manufacturing of the branded product which may use set of excipient to enhance the bioavailability that may still be under patent of the brand manufacturing or the original manufacturer while the quality of generic product remains the same, such as: essential qualities i.e. as intended use, safety, efficacy, quality and other performance characteristics as that of branded one. Documentation of generic manufacturing requirements and seeking of permission from the brand manufacturer under the deceleration of Helsinki. (Revised D.O.H.).

R.xii.) Reports on ethics committee and details on the I.P. procedures and its administration data or details made in writing to the P.I. by the sponsored or sponsoring company or by the P.I. itself.

R.xiii) Assessment of the study procedure, techniqualities involved, study of I.B., finding of risk, risk based assessment of the protocol designing should be verified before conductance of the study.

R.xiv.) Review on safety of the I.P. to be used in trial must be submitted in reports to I.R.B. and the ethics committee for the further review of subjects and the criticality.

R.v.) Identification of risk and potential threats is the major role of P.I. and other site staff such as HCP involved in the study, before processing any trials.

R.v.i.) This includes review on reports on toxicity studies.

R.v.a.) To study and review toxicology and reviews of chemical and biological data on the mentioned study of drugs to identify if any potential cause of toxicity occurs after administration of the I.P./trial drug or drugs.

R.v.b.) Literature research and safety data on/including (preclinical and clinical studies).

R.v.c.) Collection of details of ingredients and consumer product safety assessment before any evaluation or conductance.

R.v.d.) Literature review for hazard assessment of ingredients intended to be used in consumer products.

R.v.e.) Assessment of fragrance and flavours used if any; to mask the bitter odour, taste and also fishy odour of the drug material or the I.P. used in consumer products.

R.v.f.) Toxicology; risk based assessment for formulation of cosmetics application including margin of safety calculations in the I.P. and formulations.

R.v.g.) Assessment of skin tolerance of cosmetic ingredients and products from preclinical and clinical perspectives; also includes assessment of I.P. and formulation of topical preparation.

R.v.h.) Reviews and interpretation of clinical study for skin safety studies including (patch test, phototoxicity of drug in exposure to sunlight), photosensitivity, irritation and sensitization studies in both cosmetics and topical pharmaceutical preparation. This also includes some of the herbal preparation.

R.v.i.) Review of I.P. products at different stages of development cycles.

R.v.j.) Assessment of OTC products and impurities/ impurity qualification.

R.v.k.) Preparation of technical justification, report for regulatory submission.

R.v.k-i.) This includes atlas headings of drugs and drug reports.

a) Such as: drugs; categories; whether had pass first pass effect or not

Atlas heading includes (Titles), mapping of these drugs under the particular categories. Such headings are made in writings; such as

a.i.) Drugs that stop progression of COVID-19 disease/ Parkinsons disease.

b.ii.) A new experimental drug has displayed success in stopping the progression of pandemic/epidemic caused by SARS-CoV-2. (COVID-19)/ Parkinson's disease, studied in animal models, such as mouse.

c.iii.) An experimental drug development at Johns Hopkins medicines centre found to stop the progression of Parkinson's disease in live mice models.

d.iv.) Compelling new drugs that researchers had developed called NLYOI, and it is similar to a group of drugs already used in humans to manage insulin levels for type 2-diabetes.

b) Categories

b.i.) Drugs that stop COVID-19, Parkinson disease or diabetes etc.

b.ii.) Drugs that stops viral protease inhibitors, Nucleotide analogy.

b.iii.) Details on first pass effects: **b.iii.a.)** Passes first pass effect. **[✓]. b.iii.b.)** Does not pass first pass effect. **[×]**. **b.iii.c.)** Unavailable details. **[-].**

R.vi.) Assessment, collection and maintenance of I.C.F., of all the study subjects and maintained then after the study for the regulatory requirements/purposes.

S.) Understanding and making the consent of P.I. availability throughout the study including the team throughout in the study.

S.i.) Availability of study details and time period the study to be conducted and the purposement of the designed study.

S.ii.) P.I. assessment and assent in writings to conduct the entire study at the site and handle all the studies efficiently after review of the I.B. and the assent to not to terminate the study or leave the study under any circumstances without a valid reason to terminate the study.

S.iii.) P.I. assent and assurance to conduct the study as with the designed study protocol.

S.iv.) P.I.'s assurance to well document each and every outcome honestly and scrupulously found out of the study on regularly basis and duly signed and submitted each time or weekly as per the designed study protocol along with the details of S.N. Details and signature well documented with the required data and time.

T.) Title of the study

T.i.) Includes specific title.

T.ii.) As per the P.I. or as per the sponsor details or sponsor requirements.

T.iii.) As per the I.B. information.

U.) Subject to expertise: Subject to expertise is required in the matter of concern to the study conducted to expertise the details obtained and to submit a clinical conductance detailed out come/report on behalf of P.I. that is in response obtained at the time of study. This includes critical evaluation of the subjective data obtained by the site.

U.i.) Subject to expertise is obtained as an additional data that is required for documentation in terms of expertise review obtained from another P.I. who may or may not be present at the time of study.

U.ii.) Comparative evaluation of key indications and finding of faults and clinical significance of the obtained study report from both the P.I.

V.) Review of expertise report: This includes review of expertise reports of both the P.I. sufficiently explaining the study outcomes obtained from the study or conducted trials as well from the other H.C.P's explaining the storage or requirements and maintenance of I.P. during at the time of study, including pharmaceutical report made by pharmacist on the site for the required I.P.

V.i.) Finding of lacuna, possibilities of development of the data of already registered trials of same sponsor, same drug, same sponsor, different drug. Vice versa.

V.ii) Inculcating improvements in the dosage, drug, I.P. and study conduct which includes: when reviewing a protocol it's important to connect the rights dots. Consideration on placebo controlled/washout trials whether this can be rationalised for EC/RA application, placebo justification from sponsor.

V.iii) Clarification on whether does the study involved includes children, if yes the expect S.P.C., rather than I.B. (Summary of product characteristics, SmPC, Supplementary protection certificate-EMA.). e-SPC. Study title. etc.

W.) Requirements of any changes that is in requirements of the sponsor's decision.

X.) Sponsors response in details to the obtained study details. Consideration of all the obtained responses. Sponsors' comment and review details duly signed by the sponsor.

Y.) Re-investigate an I.P. if required to be done if any details found to be missing or needed to be studied again.

Y.i.) The designment of special study reports if required in re-investigating the study.

Y.ii.) Passing of I.B. to conduct the study on conducting of the particular concerned area of study to get the right study outcome.

Y.iii.) To conduct the re-trial (conductance of re-trial.), if required. Solely depend on sponsor's decision, but mostly not required in a properly; designed, qualified, and verified

clinical study that is conducted by a qualified P.I. in a particular fashion/method of the study that is Pre-designed. and qualified to conduct the trial/study and as per the study protocol using the detail study as per I.B. particulars.

Z.) Regulatory bodies and agencies whether to pass the I.P. or to retain it for further study/completely discard it from any trials further.

2. Purpose and scope of the current study to understand COVID-19 infection as a major cause of pandemic

COVID-19 caused a state of exigent situation on earth which has led to cause a pandemic, that is raised in the patients over large population caused by SARS-CoV-2 a virus causing COVID-19 infections in human and can be equally affecting animals.

2.1. Highlights of the COVID-19 pandemic includes

The world health organization (WHO) has made into the assessment that COVID-19 (corona-virus) can be characterized as a pandemic which is caused by the virus and can affect a large population within a few time period and can spread to many countries across the globe. The purpose of this documentation is to provide clearer vision on scientific requirements and actionable guidance for safety operations throughout the pandemic and help identify the infection and its early detection, prevention and control in the public places where the chances of getting infected are more, such as school, colleges, university, offices, and other public places including transport, commute. The providence of knowledgeable guidance on current situation is a major focus of this document. This study will focus on minutiae of COVID-19 and its future preventative measures. This minutiae document expresses its qualified studies to be applicable over the countries expressing the conformance of transmission of COVID-19, which is relevant in details of the required content in the terms of context; COVID-19 a cause of pandemic and it's causative agents SARS, SARS-CoV-2. Required education and significant guidance will help the students of the school and also in issuance to public health to the knowledge of the people for the gathering and travelling in the public places. This is in terms with the safety operation, wellbeing of people and promoting public health as it is observed that the COVID-19 pandemic, seize the world and had continued to grapple the world with its effects. The significant question and the challenge is to how to resolve the crisis and ensure that how can we prevent the next occurrence of any epidemic in the future. Involving and introducing newly public health policy to ensure the prevention, safety, and wellbeing of the human population. Production of formulations,

vaccines is an immediate requirement and is an urgent challenge of emerging infectious diseases. Significant policies to distinguish masses to ensure a distinguished safety and also a clearer view to the way of life. Introduction of general terms that describing the situation caused by COVID-19 pandemic includes, 'Lock-down!' Few of the other scientific and medical terminologies such as: quarantine, self-quarantine, index person etc. Preparation, subjecting of clinical trials, testing and introduction of new P.I. (Pharmaceutical Ingredients), to cure and mitigate the SARS-CoV-2 is the major focus of the scientific communities working/striving to resolve the situation of pandemic and in bringing of such new drugs/I.P./A.P.I. to the pharmaceutical markets is a major concern of the pharmaceutical industries and research scientists/ pharmacists across the world and thus require introduction of investment, planning, processing, documentation, licensing of the NDA, filling of NDA etc. Classification of products, setup of licenses, release of orders, regulatory products release system. Thus maintaining of up-to-date knowledge with applicable regulation to avoid the spread of epidemic, support smooth functioning of day-to-day life activities of the people across globe. Self-understanding, making people understand the required knowledge to safe-guard themself and also protect the people around; is also one of the major concern that is applicable. Such education can be provided in accordance to/with the help of medical authorities, HCP, such as doctors, pharmacist, nurses etc. Via general media in issuance of public health. Use of qualifying data available for scientific communities such as: medical technologist, pharmacists, researchers' scientists, clinical chemists, biologists-virologists etc. Use of already available guidance document available with WHO, FDA by qualified authorized person only. Should also be a major source of the concerned matter of expertize to significant level of assurance in the health care industries. Informed consent form filling, collection of samples-such as: Blood sampling, urine sampling, faeces sampling in container and putting up of appropriate sample code/ labelling of the samples should be done accurately at the time of pandemic, to avoid errors and mis-sampling or sampling error and failure of detection test which would produce a liable false results. Use of trial master files, sampling master files by clinical research site workforce also checking for quality accreditation, work quality accreditation (WQI), significantly highlighting of role of quality assurance in manufacturing and maintenance of I.P. or new product and also during the time of clinical trials to produce the significant documentation work, also during manufacturing support in management of third party quality agreements to meet the specific requirements to meet the standard batch release process in time. Use of handwritten signatures and signing of every required document is a significant requirement of the Q.A. when meeting a target to audit,

valid document to be produced at the time of the FDA-inspection at the site, maintenance and records of all the possible important, required meeting agenda and meeting outcomes, which should include, purpose of meeting, start time, end time, date and time, topics covered. If any dismiss of, or cancellation of meeting then duly signed document to be maintained and including the necessary requirement of meeting, purpose, date and time and reason for cancellation, signed and kept for record. Designing and preparation of all the necessary documents, SOP's etc. that will be required to support business and timely preparations of the documents, adhering to regulatory guidelines such as FDA, GCP, ICH, SOPs, etc. Such trials; preclinical trials are included to find the clinical significance and therapeutic importance of a medication to prove its clinical cause upon consumption i.e. medication or cure. Such documents are required and mandatory to be processed as it was not required to put in force of action, until the Kefawer-Harris amendment of 1962 that pharmaceutical companies were required to prove that a medication actually treated the condition it was purported to treat, i.e. its efficacy in terms of therapeutics. Ready availability of the required informative documents is important in any cases to prevent time loss in searching and finding the information and collecting, at the time when required. Thus few of such information that can be studied directly by the investigator/P.I. to find regulatory authorities that governs the policy, procedures and process of the IRB, the P.I. could easily refer the code of federal regulations i.e. 21 CFR part 56. This includes GCP and GDP too. To have knowledge of applicable research, regulatory requirements i.e. ICH, GCP and relevant regulatory guidelines that includes regulatory documents i.e. 21 CFR part 11 and knowledge of CDISC data standards. Such procedures are required in GDD, that is global drug development process during the time of pandemics and thus needed to be documented at every single step of the research carried out. This involves GDP, good document practices. European medicines agency of science, medicines, health brings together few of the human regulatory parameters in the field of research and development. This includes few of the Pharmacovigilance procedures and materials such as: **1.)** Collection of adverse drug reaction's data from the valid sources. **2.)** Scientific communication. **3.)** Improvements in the quality management systems. **4.)** Life-cycle pharmacovigilance. This includes the best practices on available documents, data, and implementation of best practices that can be used in marketing authorization, healthcare professionals, patients and consumers organizations. EMA, the European medicines agency in November 2013, the national competent authorities initiated the strengthening, collaboration for operating pharmacovigilance in Europe (SCOPE), which is a joint action to support pharmacovigilance operation in the European network, to minimize duplication of

work. General advisory board of the projects. Ready availability of the required informative documents is important in any cases to prevent time of loss in searching and finding of the information and collecting at the time when required.

2.1.1. Few of the SCOPE guidance includes

1. Detection of duplicates, **2.** Learning materials, **3.** Additional monitoring, **4.** Awareness levels of national ADR reporting systems. **5.** Telephonic reporting. **6.** Promoting ADR reporting, **7.** I.T. systems for adverse drug reporting. **8.** Risk communication, indication such as: (KRI). **9.** Quality management systems. (QMS), (Quality system processes). **10.** Exchange of information between pharmacovigilance assessors and inspectors. (Marketing authorization holders (MAH)). **11.** Quality planning and quality objectives. **12.** Resource management. **13.** Life cycle pharmacovigilance. **14.** Assessment of post-authorization safety studies. (PASSs). **15.** Assessment of periodic safety update reports (PSUR) and PSUR single assessment. (PSUSA). **16.** Assessment of risk management plans. **17.** Safety referrals assessed by the Pharmacovigilance Risk Assessment Committee (PRAC).

2.2. General precautionary guidelines

a. Maintaining social distancing: stay at home as much as possible as per U.K. guidance, stay 2 meters or 6 feet away from each other in public. Wear all protective gear to cover body and use a mask. Use of personal protective care equipment such as a protective mask of rating N95 or higher. Do not share your mask with anybody or use a common shared mask on a compassionate bases to fulfil the requirements at any time.

Figure: 3. Best precautionary practices during the time of epidemic/pandemic.

b. Use of good recreation during the stage of lockdown to combat any emotional stress, sever emotional stress, to combat feeling of loneliness, isolation and depression leading due to isolation. Use of effective social media and telephone connectivity to best suite with the required user interface to get the sufficient help, support, be fearless of isolation, during the phase of isolation caused due to pandemic, lockdown. **c.** Medications: keep continuing your medication as prescribed by the doctor. Keep your first aid box ready at the time of emergencies. If any signs or symptoms of fever observed, immediately consult a doctor for diagnosis. **d.** Use proper hand washing practices using proper sanitizers. Practice hygiene wherever possible and required.

2.3. Few of the questions addressing the pandemic

a. How and when will the pandemic end?

Answer: According to available guidance from the scientific reports and observing the R_0 value of the virus (WHO,2020.), it can't be predict how long will it take to stop or end the pandemic, however pandemics last from six months to years as the infected population is high.

b. How dangerous is COVID-19?

Answer: Although for most people COVID-19 caused only mild illness, it can make some people very ill. More rarely, the disease can turn fatal in a period of time and can cause immediate death due to lack of medication. Older people and those with pre-existing medical condition, such as high blood pressure, heart problems or diabetes appeared to be more sensitive or vulnerable to this infection caused by SARS-CoV-2. (WHO 2020 Situation report.).

c. Who are the high risk category to be affected by the SARS-CoV-2?

Answer: The high-risk category population are those who are healthy and can quickly get affect with the viral infection on being exposed to the infection from the index person. e.g. school, college, university students. Office going communities, mass commute in public transport. Geriatric and neonatal population are the high-risk category population facing challenges at the time of pandemic and thus need to be safeguarded from the infection of SARS-CoV-2.

d. What about diet and nutrition during the phase of viral infection or for other healthy people during or after pandemic? (World Food Programme). (WFP).

Figure: 4. Best nutrition practices during the time of epidemics or throughout day to day life including WFP tips.

Answer: Yes, diet does plays a vital role in moderating and combating disease by helping the body to get vital nutrients and rejuvenate the body and build immune power to fight the disease. Includes: carbohydrate, proteins, fats, fibres and vitamins. Drink lots of water during the time of pandemic. Water helps to keep the body healthy and also helps to keep the body fresh and vitalized with minerals and it also helps keep toxins free from the body, i.e. eliminate toxins and bacteria, virus from the body. Use in the form of pure, purified water for drinking/ in forms of sherbet.

3. Development of new medication includes clinical trials with proper solutions

There is an unprecedented morbidity, mortality and disruption of economies due to the pandemic caused by SARS-COV-2. Development of safe, effective and deployable quality vaccines are in an urgent need and are require to combat the epidemic caused by SARS-CoV-2 virus. (COVID-19). Challenging vaccines that would be needed to mitigate the consequences of pandemic and also will prevent the future outbreak. The recent responses in COVID-19 includes the acceleration study and investment in the preclinical and clinical testing, manufacturing of multiple vaccine candidates, with efficacy trials in the U.S. anticipated to be initiated in July 2020. This includes: **1.** Protocol design, **2.** Phases of trial-phase-I, Phase-II b/III trials and phase IV trials. The scope of evaluating newly developed medication includes significant evaluation of I.P. by the investigator. This includes initiation of trials. Implementing robust quality procedures is an factor for guaranteed growth in

increasing pharmaceutical market. To conduct clinical trials there is a requirement of: site identification, patient recruitment, global laboratories or access to central laboratories around the globe. For better outputs-patient safety, data quality and operational efficiency, it is required to have a clinical trial systems and designing of standard protocol with novel development and robust process and approaches. This includes models like: risk-based monitoring (RBM) and monitoring of trials, data collection and managing, managing data quality and subject safety which helps to enhance patient safety and improve data quality. Management of data using recording systems and use of a standard; regulatory information management (RIM), this will also include submitting of a multi-layered new drug application (NDA) and marketing authorization application. (MAAs.). Executing label conditions and label changes and practices across variety of countries. Data management and use of innovative data management solutions. Data management helps in management of safety data of: high quality that is required to be maintained for: **1.)** Engage patients, **2.)** Keep patient records, **3.)** Allow for early problem solving, **4.)** Ensuring data quality, **5.)** Reducing oversight time. Use of interoperable systems to develop an agnostic platform to clinical development. Use of biostatics for analytical and complexities in the study, evaluation study, prepare study patterns of a comprehensive quality to produce a statistical data which is easy to evaluate the hypothesis conduct of any required or proposed projects or study or management of budgets. Use of evidence data of early recognised finding out of trials to demonstrate value and outcomes. Such value and outcomes from gathering and combining advanced analytics with in parallel data to a statistical scalable quality and also support external comparator to accelerate drug development. Determination of the potential key risk indicators.

3.1. Cause and significant clinical evaluation of: allergy, asthma and clinical immunology and treatment or prophylaxis

Treating up allergies and combating its significant cause is the key and important functional in the treatment of such arisen conditions caused by SARS-CoV-2, including common cold, asthma.

3.1.1. Potential to an effective vaccine

A recent study by Monash University, has shown the role of plasma cells and their longevity played in the effectiveness of vaccines in the body and suggests that components within vaccines designed at the significant levels.

3.1.2. Unlocking the key to an effective vaccine

I. Snippet: The criticality of success of a vaccine stands by its ability to produce antibodies; exclusively by the plasma cells (blue). Plasma cells require continued support from specific cells that surrounds them (shown in different colours, colours like: pink, green, and yellow.). The plasma cells to have capacity to produce the relevant required antibodies to stay alive, which signify the role of the developed vaccines. This is in support of COVID-19 outbreak; that many research carried out focussed on development of vaccines and the evaluation of significant activity of the successful vaccines is based on following parameters:

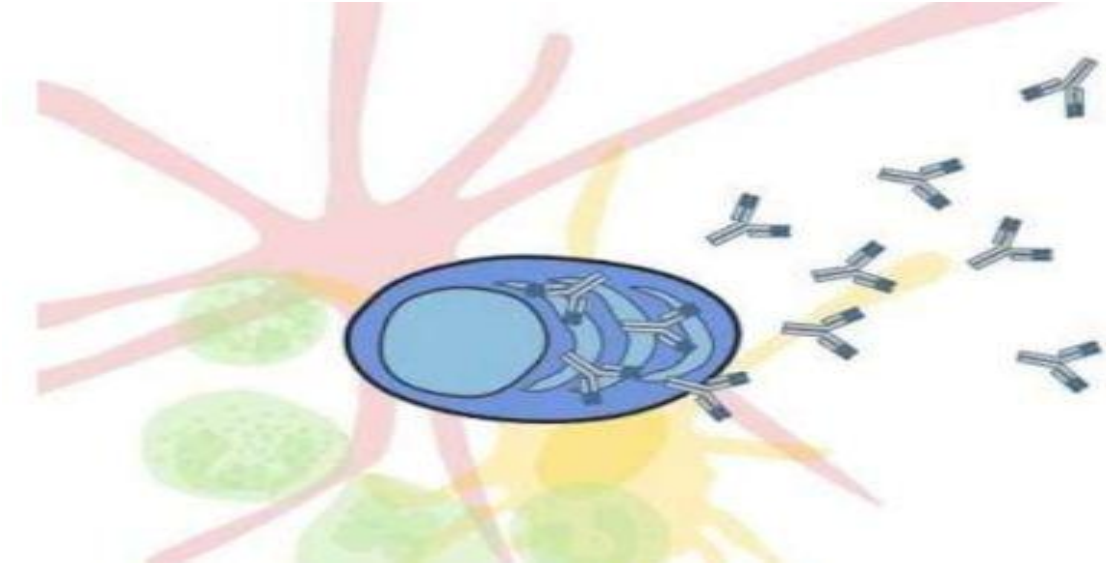


Figure: 5. Criticality to success of antibody production by use of vaccine.

3.1.2. A. For a vaccine to be successful, it has to qualify or pass two things

i.) It must signal the body to generate a lot of plasma cells making anti-virus-anti-bodies.

ii.) Second, these plasma cells have to live and produce antibodies for years or even decades for the vaccination to succeed.

iii.) Snippet: It has been past six months, being over to the newly introduced term COVID-19 caused by SARS-CoV-2; a virus causing pandemic and severe acute respiratory syndrome, termed as: 'The corona-virus infection.' Most of the scientific theories support it to be the most deadly virus on the earth that had cause pandemic condition. Reports suggest to meet a combating drug Remdesivir by Gilead Sciences.

3.1.3. Few of the study reports in the field of immunology

A recent study published in the journal of immunological reviews, led by Professor David Tarlinton from Monash central clinical school's immune memory laboratory, suggests that components within vaccines can play a major role in aiding the lifespan of individual plasma

cells. Understanding the processes involved in long-lived plasma cells formation will open up ways of making vaccine more effective. The studies also reports on criticality in designing of the vaccine: one of the difficulties in designing an effective vaccine is that it is unclear exactly what determines how long a single plasma cell will survive. As per Professor Tarlinton, the study also focuses on cusp and nib of understanding the complicated sequence of events in designing of vaccines.

3.1.4. Report on use of Pseudo-virus in treatment of SARS-CoV-2

In a recent study report published in a scientific article, "Emerging microbes and infectious journal, establishment and validation of a Pseudo-virus neutralization Assay for SARS-CoV-2," scientists from the, 'National Institutes For Food and Drug Control,' (NIFDC), have identified the new S-protein as the point of entry for the corona-virus, starting the process of infection and a significant key to produce immoral and cellular immunity to fight virus. (Perkin Elmer 2020).

3.1.5. The resurgence of convalescent plasma therapy

Trials are underway to see whether blood products from people who have recovered from COVID-19 can help boost the immune response of people with severe infection. The report suggest that the virus is targeted and destructed by other immune cells; about from the people who have recovered from COVID-19 possess to have specific antibodies.

3.2. Development of SARS-CoV-2 vaccines, for controlling of human infection

A controlled human infection models (CHIMs) have been proposed for the development of SARS-CoV-2, includes strategy for accelerating development with ethical considerations for, 'Accelerating COVID-19 Therapeutics Interventions and Vaccines,' (ACTIV) a vaccine working group had focused on the practical considerations relevant to the development of a SARS-CoV-2 CHIM and the prerequisites for using such a model. Traditional vaccine development progresses from preclinical to clinical phases and then to vaccine licensing and production at scale. A great challenge is a virus with potentially attenuating mutations may mitigate that risk, through such modification. (e.g. by site-directed mutagenesis, codon de-optimization, or serial passage), would increase development time. Critically, a rescue therapy should be available, since even well-established CHIMs have resulted in unexpected sever illness. Conduction of CHIM requires site to have facilities with biosafety level 3 laboratories for handling the virus, appropriate airborne-infection isolation rooms and access to intensive care facilities. (Meagan E. Deming et al 2020.).

3.3. Russia's approval for the antiviral drug to treat COVID-19

An influenza based medication is in clinical trials, reports the research scientists. Glenmark pharmaceuticals announced that Favipiravir is under phase III clinical trials. I.P. Avifavir, is a most promising anti-SARS-CoV-2, drug in the world as described by Russia in a literature; which is derived from Favipiravir. Favipiravir is available under the name Avigan for influenza and is recommended for the viral infection such as: **1.)** Bunyavirus, **2.)** Filovirus, and **3.)** Adenovirus. It is prescribed in case of; Severe Fever with: Thrombocytopenia Syndrome, (SFTS), a viral haemorrhagic fever with high fatality rate; and is effective against all strains of influenza viruses. Antiviral and vaccines both are equally important. Favipiravir, possess the inhibitory action against viral RNA-dependent, RNA polymerase (RdRP) of virus as per the virologist. The RNA polymerase is a viral enzyme that helps in replication or reproduction of the viral RNA in the host that is the genetic material. Hence, a drug that would inhibit the activity would significantly curb and restraint the functional multiplication of the virus. Glenmark announced a new randomised study in, 'India,' to test the combined efficacy of Favipiravir and another antiviral drug, Umifenovir as a potential COVID-19, 'treatment strategy' for clinical and therapeutic significance in treatment of SARS-CoV-2. Glenmark reported on its conductance of phase-III clinical trials of Favipiravir as a COVID-19 therapy option with 150 patients enrolled in the trial. RDIF CEO Kirill Dmitriev commented that Avifavir to be most promising anti-COVID-19 drug in the world, the RDIF and the ChemRar group announced that Avifavir has received a temporary registration certificate from the Russian ministry of Health. Favipiravir has an earlier reported action of inhibiting the influenza virus RNA-dependent RNA polymerase. Glenmark Pharmaceuticals first received the approval from the drug regulatory authority of India (DCGI)-drug controller general of India to conduct Favipiravir clinical trials against COVID-19 in India. Favipiravir is an oral antiviral drug approved in Japan in the year 2014 for the treatment of novel or re-emerging influenza virus infections. The U.S. pharmaceutical company Gilead Science receives India's drug regulatory market authorization for Remdesivir for restricted emergency use on hospitalized COVID-19 patients. The immediate approval was made to unmet need of medicines of the corona virus in the emergency situation.

3.4. Preliminary report on Remdesivir for the treatment of COVID-19

a) Snippet: Remdesivir for the treatment of COVID-19 preliminary report. Although there are several therapeutics agent that have been evaluated for the treatment of corona virus disease 2019, (COVID-19), more T.A./I.P. have been shown to be efficacious. The study

conducted a double-blind, randomized, placebo-controlled trial of intravenous Remdesivir in adults hospitalized with COVID-19 with evidence of lower respiratory tract infection patients involvement for the study. Remdesivir 200 mg, placebo both in randomised controlled trial, a total of 1063 patients had underwent randomised trial for Remdesivir. **Remdesivir (GS-5734)** were reported with inhibitor of the viral RNA-dependent, RNA polymerase with inhibitory activity against SARS-CoV-2 and MERS, Middle East Respiratory Syndrome. In the study serious adverse events were reported for 114 of the 541 patients in the Remdesivir group. The data and the safety monitoring board reviewed results, for the double-blind, randomized placebo controlled trial of I.V. Remdesivir conducted for COVID-19 patients on **27-April-2020.** The trial protocol was approved by the institutional review board, I.R.B. at each site (or by a centralised institutional review board as applicable.). Informed consent form was obtained from each patients. Thus Remdesivir is an important first step in disease management.

3.5. Other medications include to be beneficial for the treatment of COVID-19

i) Lopinavir, **ii)** Ritonavir, **iii)** Tosilizumab, (Actemra), (Monoclonal Antibodies). **iv)** Itolizumab, (Alzumab), (Monoclonal Antibodies). etc. **v)** Lopinavir and Ritonavir for severe COVID-19, Open-label randomized clinical trial of Lopinavir-Ritonavir for the treatment of COVID-19 in 199 infected adults' patients, studies for clinical improvement by investigators in China. **iv.)** Dexamethasone, B.P., A trial conducted in U.K., United Kingdom states that the drug reduces mortality in SARS-CoV-2 patients who required oxygen support. (WHO, 23-June-2020).

3.5.1. Classification of the drugs

i.) Lopinavir, Ritonavir, Duranavir-HIV protease inhibitor. **ii.)** Remdesivir-Nucleotide analog. **iii.)** Umifenovir-Influenza Antiviral. **iv.)** Favipiravir-Viral RNA-polymerase inhibitor. **v.)** Oseltamivir-influenza neuraminidase inhibitor. **vi.)** Danoprevir-HCV protease inhibitor. **vii.)** Ribavirin-Nucleotide analog. **viii.)** Tetrandrin-Ebola viral entry inhibitor. **ix.)** Dexamethasone B.P.-moderates mortality or lowers mortality in SARS-CoV-2 patients. (U.K.).

3.6. Accelerating COVID-19 vaccines development with pseudo-virus

It is a significant time for the pharmaceutical companies to come up with the developed vaccines for the infectious disease, COVID-19, caused by corona-virus; SARS-CoV-2. The virus is potent in human and animals and causes virulence to infect host cells in animals or

humans. As viruses constantly evolve in a period of time, there is a new, agile requirement for newly developed novel research in the field of biology and serology in introduction of new vaccines to save the mankind on earth. To stop this evolving virus in a period of time, there is a requirement of new, agile research applications that are in requirements to combat the evasive intruders that affects and exploit host cells. The handling of these pathogens required/need to take place in research laboratories that are designated as biosafety level-3 or higher due to its dangerous infectious nature. Thus these requirement of such high safety measures which are essential for the research safety and safety of scientific community carrying research; can extend the time period required to develop a vaccine. Additionally, procuring the live virus for an evaluation assay is very difficult and requires intensive technical labour. (In terms of safety handling.). (Safety procedures.).

3.6.1. Importance of the pseudo-virus

As these is a great significance of the versatility and safety, use of biotech tools such as pseudo-viruses which can be used by virologist as an alternative method to develop a vaccine for COVID-19. Experiments can be performed utilizing these pseudo-virus-based assay in facilities of biosafety level 2 or below. Pseudo-virus mimics the model of infection process of the corona-virus and thus finds an added benefit and advantage in combating danger of viral components. That is why pseudo-virus are an ideal candidate to accelerate the research and development of the COVID-19 vaccines.

3.6.2. The identification of the S protein

The S protein is a crucial target for the development of the vaccine for COVID-19. Consequently, a series of Pseudo-virus Based Neutralization Assay (PBNAs) have been developed that can generate robust, reproducible and accurate results using Ensight multimode plate reader and britelite plus luciferase substrate of Perkin Elmer. The Ensight multimode plate reader provides best luminescence detection technology available at present with the throughput rate of detection-less than 1 minute per 96-well plate and can support biologics, vaccines and small molecule research. The britelite plus homogeneous luciferase reporter gene assay system is designed to provide maximum signal intensity for assay requiring the utmost sensitivity. The testing of **SARS-CoV-2** convalescent patient sera which showed high neutralization potency and the assay is a reproducible and robust method with **low CV's (<17%).**

3.6.3. Sensitive and specific nucleic acid-based detection of SARS-CoV-2 virus

The detection of new corona-virus nucleic acid detection kit has a L.O.D. of 20 samples/mL for SARS-CoV-2ORF1ab and N genes. Human corona-virus (229E, OC43), SARS Corona-virus (plasmid), MERS corona-virus (plasmid). The kit contents: **i**. nCoV reagent A, **ii.** nCoV reagent B, **iii.** nCoV enzyme mixture, **iv.** nCoV internal standard. **vi.** nCoV negative control.

3.6.4. Simple sample type can be used to detect SARS-CoV-2

1. Oropharyngeal swab, **2.** Naso-pharyngeal swab, specimen as a flexible and simple method of testing.

Figure: 6. Oropharyngeal swab, Naso-pharyngeal swab, specimen testing, laboratory tests.

4. ICMR found to be one of the validated source for providing rapid antigen test kits for testing of SARS-CoV-2, detection of SARS-CoV-2, COVID-19 in an identifiable and suspected patient's population

The report states that the Indian Council for Medical Research (ICMR.), has validated one Indo-south Korean company for valid vendors of rapid antigen test kits for detection of SARS-CoV-2 infection i.e. COVID-19 and that it has been initiated for its approval to the regulatory bodies/authorities. This includes the test kit of SD-Biosensor; an Indo-Korean company for its valid testing kit. In the suggested report; the ICMR defended a fast tracking Covaxin. The ICMR states that the kits for testing SARS-CoV-2 are few of from following validated companies:

i. Camtech diagnostic. (Singapore). **ii.** A Gappe diagnostics (India).

iii. Rapigen Inc of South Korea, POCT services Pvt. Ltd. (India).

iv. HLL, Lifecare (India). **v.** Bhat bio-tech India.

4.1. The status of the report also suggest that there are pending responses from companies such as

i. Coris Bioconcept. (Belgium**). ii.** J.Mitra and Co. Ltd. (India) **iii.** M/S. Med source ozone biomedicals Pvt. Ltd. (India.). **iv.** Panion and B.F. bio-tech (Taiwan.). **v.** B.F. bio-tech and Formosa Biomedical Technology corp. (Taiwan.).

5. Verification of raw material safety and validation for raw materials required for drug manufacturing and preventing, FDA warning letters

Ensuring of raw materials safety and validation for ensuring the outcomes of product safety by analysing incoming excipient and active pharmaceutical ingredients (APIs), is a crucial and regulated step in pharmaceutical manufacturing. The results in non-compliance will results in an U.S. food and drugs administration form 483, causing delays to avoid FDA warning by quick and accurately verified use of raw materials using all applicable GMP (Good manufacturing practices.), as applicable. Involvement of Q.A./Q.C. procedures are required for analysis of incoming of excipients and active pharmaceutical ingredients (APIs.), which is a crucial aspect of a pharmaceutical industries to safety label the final product rights from its start that also involves Q.A./Q.C. laboratory. (cGMP), guideline i.e. current good manufacturing guidelines are required for identification and/or verification of raw materials used in the pharmaceutical manufacturing process. Failure to generate COA of the raw materials procured from a valid vendor or from a pharmaceutical manufacturing industry i.e. outsourced materials to qualify the cGMP requirements, failure to abide these cGMP guidelines and regulations can lead to issue of a FDA form 483, which demonstrate certain condition of compliance standards. If the non-compliance is more significant and can deviate or affect any procedures, or the inspected firm fails to respond appropriately to an FDA form 483, a warning letter is issued. As per a report of FDA, in 2019, over 770 of form 483, were issued and in additional to this over, 81 warning letters were issued. The most common findings/citation were violation of 21 CFR 211.84, which is the main FDA regulation related to testing of components, storage conditions and closure, drug products. Along with the FDA regulation, there are variety of other compliance documentation issued by multiple governing bodies. The most prevalent regulation includes: **i.** FDA 21 CFR 211.80-control of components and drug products containers and closures. **ii.** FDA 21 CFR 211.84-testing and

approval or rejection of components, drug product containers and closures. **iii.** GMP-good manufacturing practice, guidance section B of V117.2-receipt and quarantine of incoming materials. **iv.** ICH-Q7 code, section 6.3-records of raw materials, intermediates, API, labelling and packaging materials. **v.** European medicines GMP-chapter 6th of: Quality Control. There are different slew of regulations involved. There are major three requirements that are regulatory covered: **i.** Analysis of materials used during the manufacturing process. **ii.** Approval or rejection: approval or rejection of materials based on results of analysis. **iii.** Documentation of collected data in a traceable format, that is a qualified document, also includes use of FDA 21 CFR part 11 regulation which pertains to keeping of electronic records and electronic signatures.

6. Expert review from WHO 2020 pandemic reports and technical/scientific communication

i. Dr.Maria Van Kerkhove-technical lead COVID-19, WHO coronavirus expert. emerging disease and zoonosis unit, world health organization, spoke on people affected with pneumonia and acute respiratory distress syndrome and need of respiratory and oxygen support to frontline the requirements during the time of COVID-19, transmission of SARS-CoV-2, and airborne precaution and use of mask during the time of epidemic. (Report from, WHO 2020.).

ii. Dr. Mike Ryan (EXD, WHO Health Emergencies Programme): the SARS-CoV-2, is a disease that can spread anytime as the disease is a fast affecting disease in communities. Reports on the spread of pandemic of 1919 and the Spanish flu.

iii. Dr. Tedros Adhanom Ghelereyesus, reports that one of the most effective ways of saving lives from COVID-19 is providing oxygen to patients who need it. WHO estimated that at the current rate of~1 million new cases a week, the world needs about 620, 000 cubic metres of oxygen a day, which is nearly 88, 000 large cylinders. Highlights includes the risk of COVID-19 for some of the world's most vulnerable people. Refugees are particularly at risk of COVID-19 because they often have limited access to adequate shelter, water, nutrition, sanitation and health services.

7. WHO reports and highlights

Snippet: WHO discontinues Hydroxychloroquine and Lopinavir/Ritonavir treatment arms for COVID-19. WHO on 4th July 2020, accepted recommendation from the solidarity trial's international steering committee to discontinue the trials of/on Hydroxychloroquine (U.S P.)

and Lopinavir, Ritonavir arms. The solidarity trials was established by WHO to find an effective COVID-19 treatments for hospitalized patients.

8. Internal structure of coronavirus: (Scientific-American, 2020)

Scientist discovered the internal structure and working of pathogen that has infected the world-Mark Fischetti reports states that SARS-CoV-2 is about 100 nanometre in diameter, visible only with an electron microscope. The cross section is identified as a near sphere of protein inside a fatty membrane that protects a twisting strands of RNA, a molecules that holds the virus genetic code. Protein called 'S', forms spikes that extend from the surface and get into human cells, as the size of the virus is very small. So the particle or virion can slip inside the crown, or corona, appearance gives the virus its name. Structural proteins-N, M and E moves inside the cells, where they help new virons to form in the host cells.

1. The virus: The SARS-CoV-2, virus particles is a ball of proteins wrapped in a protective fatty coating.

2. RNA (red coloured): This twisting strand of RNA is the blueprint the virus uses to replicate itself inside of you.

3. Entry spikes (orange coloured): The virus uses its spike-shaped S proteins, which stud the surface, to grab onto human cells.

4. Protective shell: This is a lipid bilayer which protects the virus genetic cargo as it travels inside the body.

5. N protein (blue coloured): This protein help keep the viral RNA stable.

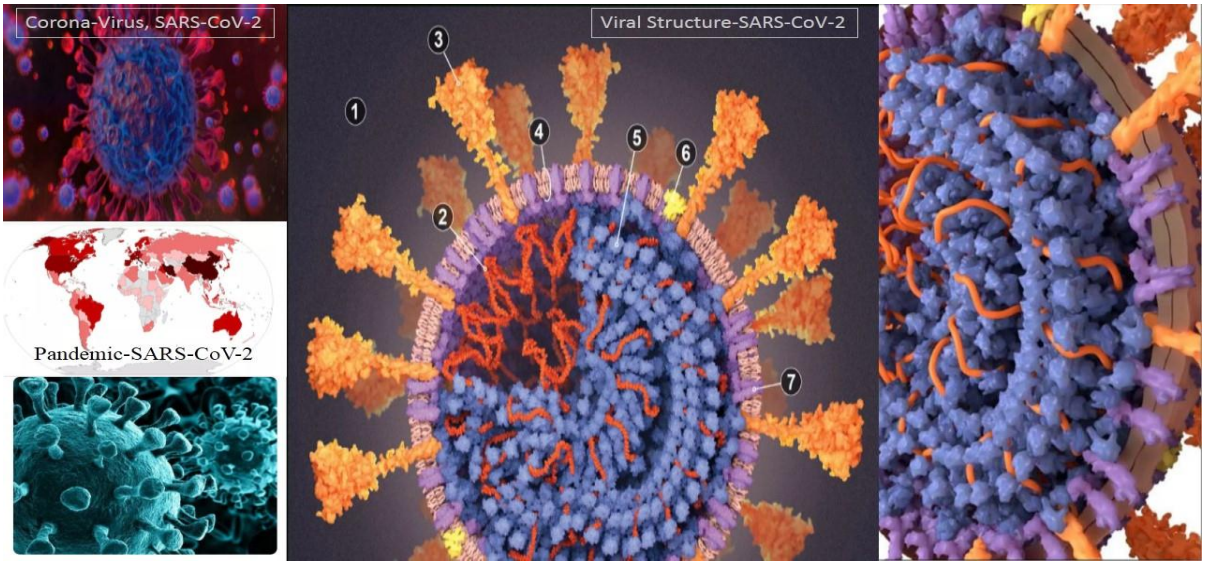


Figure: 7. Microscopic image of SARS-CoV-2 virus, and its demography in world; causing pandemic.

6. E protein (yellow coloured): This protein helps new virus particles to form.

7. M.protein (purple coloured): This is a protein that helps new virus particles to form.

9. The international accrediting organization for clinical research, link to regulatory authorities around the world

A. Australia/New Zealand

i. Australia-Therapeutics goods administration, (TGA).

ii. New Zealand-Medicines and medical devices safety authority, (MEDSAFE).

B. North America and America

i. Canada-Health Canada.

ii. USA-Food and Drug Administration, (FDA).

C. Europe

i. Armenia-Scientific centre of drug and medical technology expertise.

ii. Austria-Agency for health and food safety, (AGES).

iii. Belgium-Federal Aaency for medicines and health products.

iv. Bulgaria-Bulgarian drug agency.

v. Croatia-Agency for medicinal products and medical devices of Croatia, (Ministry of Health).

vi. Cyprus-Ministry of Health.

vii. Czech Republic-State institute for drug control.

viii. Denmark- Danish medical Agency.

xi. Estonia-State agency of medicines.

x. Finland-Finnish medicinal agency. (Finnish medicines agency/national supervisory authority for welfare and health.

xi. France-Agence nationale de sécurité du medicament et des products de santé. National agency for safety of medication and health products, (ANSM.).

xii. Germany-Federal institute of drugs and medical devices, (BfArM).

xiii. Georgia: Regulatory agency for medical and pharmaceutical activities.

xiv. Greece-National organisation for medicines, (EOM).

xv. Hungary-National institute of pharmacy. (National Institute of pharmacy and nutrition.).

xvi. Iceland-Icelandic medicines agency.

xvii. Ireland-Irish medicines agency (Health products regulatory authority.). (HPRA).

xviii. Italy-National institute of health, (Italian medicines agency.).

xix. Latvia-State agency of medicines of the republic of Latvia. Ministry of health of the republic of Latvia. Latvijas republikas veselibas ministrija.

xx. Lithuania-State medicines control agency, (SMCA).

xxi. Luxembourg-Ministry of Health.

xxii. Malta-Maltese medicines authority.

xxiii. Moldova-Medicines agency.

xxiv. Netherland-Medicines evaluation board/health care inspectorate, (IGZ).

xxv. Norway-Norwegian medicines agency.

xxvi. Poland-the office for registration of medicinal product, medical devices and biocidal products. Ministry of health.

xxvii. Portugal-National authority of medicines and health products.

xxviii. Romania-National medicines agency. The national agency for medicines and medical devices, (NAMMD).

xxix. Russia-Ministry of health of the Russian federation. Russia-Federal services on surveillance in healthcare and social development/ministry of healthcare.

xxx. Serbia-Medicines and medical devices agency of Serbia/Ministry of health.

xxxi. Slovakia-State Institute for Drug Control (Slovak republic).

xxxii. Slovenia-Ministry of health (Agency for medicinal products and medical).

xxxiii. Spain-Spanish medicines agency, (Ministry of health, social services and equality).

xxxiv. Sweden-Medical products agency.

xxxv. Switzerland-Swiss agency for therapeutic products.

xxxvi. Turkey-Turkey pharmaceutical and medical devices agency. Turkish medicines and medical devices agency, (TMMDA).

xxxvii. Ukraine-Ministry of health care. State inspection for quality control of medicines.

xxxviii. Kazakhstan-National centre of drugs, medical products and medical equipment examination.

xxxix. United kingdom-Medicines and healthcare regulatory agency, (MHRA). (U.K.MHRA.).

D. Middle East

i. Algeria-Ministry of health, population and hospital.

ii. Bahrain-National health regulatory authority.

iii. Egypt-Ministry of health and population/Egyptian drug authority, (EDA).

iv. Iraq-Ministry of health.

v. Israel-Ministry of health.

vi. Jordan-Jordan food and drugs administration, (JFDA).

vii. Kuwait-Kuwait institute for medical specialization.

viii. Lebanon-Ministry of public health.

ix. Morocco-Ministry of health.

x. Oman-Ministry of health, Sultanate of Oman.

xi. Qatar-MOH pharmacy and drug control department.

xii. Saudi Arabia-Saudi food and drugs authority, (SFDA).

xiii. United Arab Emirates-Ministry of health.

E. Central/South America

i. Argentina-National administration of drugs, food and medical devices, (ANMAT).

ii. Brazil-Agencia nacional de vigilancia sanitoria, (ANVISA). (Brazilian health surveillance agency).

iii. Chile-Instituto de Salud publico, (ISP). Public health Institute of Chile, (ISPCH).

iv. Colombia-Instituto nacional de vigilancia medicamentos y alimentos, (INVIMA). Ministry of health and social protection.

v. Costa Rica-Ministerio de Salud, (Ministry of Health.).

vi. Cuba-Ecuador:National Agency for Regulation, Control and Sanitary Surveillance, (ARCSA).

vii. Dominican Republic-Direccion General de drogas y farmacias.

viii. Jamaica- Ministry of Health.

ix. Mexico-Comision federal para la protección contra riesgos sanitarios, (Federal commission for the protection against sanitary risk), (COFEPRIS).

x. Paraguay-Ministro de Salud pública y bienestar social.

xi. Panama-Ministry of health.

xii. Peru-General directorate of medicines, supplies and drugs, (DIGEMID).

xiii. Venenzuela-National Institute of hygiene.

F. Asia Pacific (Asia and the Pacific)

i. Bhutan-Drug regulatory authority.

ii. China (People's Republic)-State food and drug administration, (SFDA).

iii. Hong Kong-Department of health/Control drugs standard control organization.

iv. India-Central drugs standards control organization, (CDSCO).

v. Indonesia-Pengawas obat dan makanan, (POM).

vi. Japan-Ministry of health, labour and welfare, (MHLW). Pharmaceutical and medical device agency, (PMDA).

vii. Korean (South)-Korean food and drug administration, (KFDA).

viii. Laos-Food and drug department.

ix. Malaysia-Ministry of health, (MOH). National pharmaceutical regulatory agency/Medical device authority.

x. Nepal-Department of drugs administration.

xi. Philippines-Department of drugs administration.

xii. Singapore-Health science authority, (HSA).

xiii. Sri Lanka-SPC, ministry of health, (MOH)/cosmetics, devices and drugs regulatory authority.

xiv. Taiwan (Republic of China)-Taiwan food and drugs administration, (TFDA).

xv. Thailand-Food and Drug Administration of Thailand Bureau of Drug Control/Medical Device Control Division.

xvi. Vietnam-Drug Administration of Vietnam/Medical devices department, ministry of health.

G. Africa

i. Algeria-Ministry of health and population and hospital.

ii. Botswana-Ministry of health, (MOH).

iii. Burkina Faso-Le ministère de la Santé.

iv. Ghana-Food and drugs authority.

v. Kenya-Pharmacy and poisons board, (PPB).

vi. Nigeria-National agency for food and drug administration and control, (NAFDAC).

vii. Rwanda-Ministry of health.

viii. Senegal-Ministère de la Santé et de l'action sociale.

ix. South Africa-Medicines control council, (MCC)/Department of health.

x. Swaziland-Ministry of Health.

xi. Tanzania-Tanzania food and drug authority, (TFDA).

xii. Uganda-National drug authority.

xiii. Zimbabwe-Medicines control authority of Zimbabwe, (MCAZ). State government office in Harare, Zimbabwe.

10. Organizations and standards

Table: 1. Organizations and Standards.

i. The European medicines agency, (EMA). Protects and promotes public health through the evaluation of medicines.	**ii.** Australia, New Zealand therapeutics products, (ANZTPA). (IQVIA-Headquarters, headlines report.).
iii. Asian harmonization working party, (AHWP).	**iv.** Association of South-eastern Asian Nation, (ASEAN).
v. Council for International Organization of Medical Sciences, (CIOMS).	**vi.** International Conference on Harmonization-ICH.
vii. International Medical Device Regulators Forum, (IMDRF).	**viii.** International Organization for Standardization, ISO.
ix. MedTech Europe Med-Tech Europe. **MERCOSUR**	**x.** Organization for Economic Co-operation and Development, (OECD).
xi. Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme, (PIC/S).	**xii.** World Medical Association, (WMA). **xiii.** World Health organization, (WHO).

11. FDA granted LOA and letter granting inclusion under EUA. (FDA)

1. E.g. A. Individual EUAs for molecular diagnostic test for SARS-CoV-2

Table: 2. Few of the LOA issued by FDA.

Date EUA issued	Manufacturer name	Diagnostic, (letter of authorization).
06-29-2020	Life Hope Labs	Life Hope 2019-nCoV real-time, RT-PCR diagnostic Panel.
06-26-2020	Inform Diagnostic, Inc.	Inform Diagnostics SARS-CoV-2, RT-PCR Assay.

2. Appendix A: Authorization molecular-based laboratory developed tests for detection of nucleic acid from SARS-CoV-2.

Table: 3. Few of the letters granted for authorization molecular-based laboratory developed tests for detection of nucleic acid from SARS-CoV-2.

Date EUA issued	Laboratory	Letter Granting inclusion under EUA.
06-12-2020	Cormeum laboratory services	Cormeum SAR-CoV-2 assay.
06-10-2020	Warrior Diagnostics Inc.	Warrior Diagnostics SARS-CoV-2 Assay.

12. Corona-virus vaccine candidate developed in Adelaide laboratory

Adelaide laboratories succeed in developing corona-virus vaccine candidate, which is subject to human trials. This is a potential corona-virus vaccine developed in Australia and is based on a protein found in insect cells and are about to begin in Adelaide. Trial to be conducted at the site, 'Royal Adelaide Hospital.' If successful, the vaccine candidate will be tested on higher risk individuals. States the scientific report with research director, Professor Nikolai Petrovsky. The vaccine was developed by Adelaide-based Company, Vaxine, which has

laboratories at Flinder University.

Figure: 8. SARS-CoV-2 medication and vaccine development.

13. List of abbreviation that are commonly used

1. Accelerating COVID-19 therapeutics interventions and vaccines, (ACTIV).	**38. Interstitial lung disease, (ILD).**
2. Active pharmaceutical ingredient, (API).	**39. Investigational medicinal products, (IMPs).**
3. Adaptive COVID-19 treatment trials, (ACTT-1).	**40. Laboratory developed tests, (LDTs).**
4. Advanced sterilization systems, (ASP).	**41. Legally acceptable representive, (LAR).**
5. Analytical method validation, (AMV).	**42. Live Modified organisms, (LMO).**
6. Chemical manufacturing control, (CMC).	**43. Low molecular weight heparins, (LMWHl).**
7. Chronic obstructive pulmonary disease, (COPD).	**44. Ministry of health, (MoH).**
8. Clinical laboratory improvement amendments, (CLIA).	**45. National competent authorities, (NCAs).**
9. Clinical laboratory improvement amendments, (CLIA).	**46. National Institute for food and drugs control, (NIFDC).**
10. Comparative dissolution profile, (CPD).	**47. National institute of biology, (NIB).**
11. Contact commercial organization, (CCO).	**48. New chemical entity, (NCE).**
12. Contract manufacturing organization, (CMO).	**49. Next generation sequencing, (NGS).**
13. Contract research organization, (CRO).	**50. Over the counter, (OTC).**
14. Controlled human infection models, (CHIMs).	**51. Paediatric committee, (PDCO).**
15. Data and safety monitoring board, (DSMB).	**52. Paediatric investigation plan, (PIP).**

16. Department of bio-technology, (DBT).	**53. PAN American health organization, (PAHO).**
17. Drug controller general of India, (DCGI).	**54. Periodic safety update report, (PSUR).** **55. Personal protective equipment, (PPE).**
18. Early clinical development, (ECD).	**56. Pharmacovigilance risk assessment committee, (PRAC).**
19. Enzyme linked immuno-sorbent assay, (ELISA).	**57. Pharmacovigilance safety assessment programme, (PSAP).**
20. European medicines regulatory network, (EMRN).	**58. Process validation, (P.V.).**
21. European network of centres for pharmacoepidemiology and pharmacovigilance, (ENCePP).	**59. Pseudovirus-based neutralization assays, (PBNAs).**
22. Extracorporeal membrane oxygenation, (ECMO).	**60. Qualified person, (QPs).**
23. Food business operation, (FBO).	**61. Rapid diagnostic test, (RDT).**
24. Functional service provider, (FSP).	**62. Reference biologics/bio-therapeutics products, (RBP).**
25. Gel permeation chromatography, (GPC).	**63. Review committe on genetic manipulation, (RCGM).**
26. Genetic engineering appraisal committee, (GEAC).	**64. Risk management plan, (RMP).**
27. Good laboratory practices, (GLP).	**66. Safety of blood, tissue and organs, (SaBTo).**
28. Ground glass opacity, (GGO).	**67. Similar bio-therapeutics products, (SBPs).**
29. Heads of medicines agencies, (HMA).	**69. Single molecule counting, (SMC).**
30. Health care-provider (HCP).	**70. South east Asia regulatory network, (SEARN).**
31. Health protection team, (HPT).	**71. Subsequent entry biology, (SEB).**
32. Infectious bronchitis virus, (IBV).	**72. Supplementary interactive plotted data, (SIPD).**
33. Informed consent form, (ICF).	**73. U.S. National Institute of Allergy and infection disease, (NIAID).**
34. Institutional review board, (IRB).	**74. United nations office on drugs and crime, (UNODC).**
35. International biosafety committee, (iBSC).	**75. Universal health coverage, (UHC)..**
36. International coalition of medicines regulatory authorities, (ICMRA).	**76. World intellectual property organization, (WIPO).**
37. International non-proprietary names, (INN).	**77. Zero discharge hazardous chemical, (ZDHC).**

14. Few of the natural remedies for the treatment of SARS-CoV-2 conditions include

Few of the natural remedies for the treatments of SARS-CoV-2 conditions includes symptomatic treatments for the betterment of the disease condition in humans and animals. (Mitigation), using natural medicines/herbal medicines. Use of antitussive agents naturally

obtained from the plant sources to treat cough and upper respiratory tract infections, respiratory problems. This includes: 1. Adathoda Vasaca, (Adathoda Vasica), which possess phytochemicals to treat the condition are: Vasicine, Vasicinolon. 2. Glycyrrhizaglabra-(Liquorice), containing-Glycyrrhizin, 3. Shatavari, containing Shatavarin, which is used for immunity boost and also as an natural aphrodisiacs (aphrodisiakos.), in men and a vitality boost or strength builder in women. Thus need to be used properly in management of immunity boost during the time of pandemic. 4. Ginger, including phytochemical constituents such as: a. Gingerol, b. Zingiberene, c. Zingerone and, 5. Allisin from Garlic, this is a potent antifungal agent, an expectorant and also manages blood cholesterol levels. Use of bitter-gourd juice (Momordica charantia), (bitter apple, bitter squash, bitter balsam-pear.), to enhance and fight the multiplication of virus in the host. This is potential in treating viral infection, along with water. Maintenance of body temperature is must during the time of such remedy as bitter-gourd juice can be a product which can cause coldness of the body due to its activity. (So can be taken with honey and jiggery, with clove buds powder). (Raw juice of Momordica Charantia). Few of the reputed sources of manufacturing companies that prepare dosage forms of herbal or natural based drug materials includes: Himalayas, Natural Concepts, Patanjali and Divya Pharmacy, Vicco, Dabur.

15. CONCLUSION

SARS-CoV-2 is the leading cause of pandemic noted at this time which is a zoonotic virus and had affected the planet earth. There are efforts taken by scientific communities and researchers along with health care professionals to diagnose, evaluate and treat this disease condition caused by the SARS-CoV-2 virus. This efforts come through best practices from in designing and formulating medicines. Medicines such as: Remdesivir, Hydroxychloroquine and Lopinavir, Ritonavir, Favipiravir, Umifenovir went through the clinical studies and had been studied for its prophylaxis in treatment of SARS-CoV-2, a COVID-19 infection. Amongst all Remdesivir, Favipiravir, Umifenovir found to be effective in treating the SARS-CoV-2 condition in patients. i.e. prophylaxis of SARS-CoV-2. Development of the Vaccine called Vaxine was developed by the Adelaide, in laboratories of Finder University, and is under the clinical trials for its efficacy in boosting the immunity against the SARS-CoV-2 virus. There are various regulatory bodies or regulatory agencies working around the globe to approve the use of proven drugs in the particular countries and thus there may still be requirement of Phase-IV evaluation if any to be found over the large population. Involvement of GCP, GDP, ICH, and regulatory authorities around the globe/world can be studied

definitely, that are involved in the regulation of food and drug materials for the health and safety of the people/population. WHO coronavirus expert Dr.Maria Van Kerkhove-technical lead COVID-19, reported on pneumonia and acute respiratory distress syndrome that had affected people and the need of respiratory/medicated oxygen support, is an urgent requirement for the hospitalized patients; diagnosed with SARS-CoV-2 along with required medication.

16. ACKNOWLEDGEMENTS

The author would like to express vote of thanks to the "World Journal of Pharmaceutical Research," to recognize the work and publish it in the journal.

17. CONFLICT OF INTEREST

Author declares no conflict of interest regarding the publication of this article.

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