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Interview

It was not possible without husband and family: CSIR NET Life Science topper 2020

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Interview

It was not possible without husband and family says CSIR-JRF-NET-June 2020 topper

This year, Aditi Godara has secured rank 1 in CSIR -JRF-NET Life Sciences exam. Biotech Express got in touch with Aditi Godara to learn more about her preparation strategy. Here are the excerpts.

How you are feeling and how will you celebrate your success?

The feeling is surreal. Its been a week now, since the results were out but still I'm euphoric about it. I think the happiness and pride on my husband and parents' face is my celebration in itself.

When did you start your preparations for the NET exam? Is this your first attempt?

I have been serious with life science throughout my bachelors and masters as there need to be a strong background behind rank 1. It's a fruit of years of hard work. Still to name, I started preparing for June 2020 from October 2019; It was my second attempt. My first attempt was in first year of my masters which followed a major eye surgery that took me months to recover and there was no other attempt for two years. After post graduating I got married and I almost thought to quit this exam altogether, but then my husband who is my biggest inspiration asked me that you shouldn't give up anything you wanted to do. 'Our life journey will always have good additions and no subtractions' he said.

How challenging it was to prepare for NET?

Vastness of syllabus is itself most challenging thing about this exam.

How did you plan your preparations?

There are 13 units in the syllabus. At one time, I would run 3 units dividing my day into 4 parts in which 4th part would only have revisions. so, this is how I planned my preparations. I have been thorough with all topics because superficial knowledge never helps in this exam. I inculcated quick and repeated revisions in my daily schedule since its important to keep topics fresh from beginning till end of the preparation span.

When and what inspired you to go for research?

I just love science and I have been always a very curious student. I would frequently ask "how" and "why" for the information delivered to me by my teachers. I think this is where it comes from.

In which research institute you as-

pire to take admission?

IISc is dream for me but since it is a very sensitive pick as it will be a long journey ahead so I will take some time to decide.

How did you manage to prepare for NET during the lockdown? Had it affected your preparation?

Lockdown phase was initially very disturbing because exam got postponed and there was no date announced for 5 months but it eventually turned out to be an advantage as we could revise and practice more. This phase required a lot of patience and we had to keep ourselves strong and firm.

How much support you got from your college and university teachers?

A -I did my graduation from a private college in a small city where focus is more on clearing exams rather than learning. But few of my seniors were very helpful and they exposed me to some good reference books-

1. Lehninger for Biochemistry; 2. Watson for Molecular Biology; 3. Bruce Alberts for Cell Biology; 4. Kuby for Immunology; 5. Snustard and Simmons for Genetics; 6. Gilbert for Developmental Biology; 7. Taiz and Zeiger for Plant Physiology

I used to visit Library and started studying these books. So, I would like to communicate this to aspirants that if you also feel that college lectures are not helpful, start reading good books as a good reference book is the finest teacher.

And start reading these books during Graduation only as it will take time to be covered.

Luckily, I got to study from really distinguished Professors during my post graduation from Department of Botany, Panjab University Chandigarh. Prof. Harsh Nayyar and Prof. Daisy Batish taught us Plant Physiology and Ecology respectively and these two units (out of 13) got prepared during then only.

Did you take any coaching for NET 2020? By what means you were in touch with your teachers for doubts regularly during the lockdown?

I had my mentors from Pathfinder Academy. Took their classes and also read dedicated reference books for several topics alongside since they are important for the background story behind a concept which helps a lot in solving part C questions which are meant to test one's research aptitude and scientific temper. So there were lot of personal efforts besides coaching. I used to clear my doubts through online discussions and over phone call with my mentors.

Which subject is your weak and which one is strong?

I had my masters in Botany from Panjab University, Chandigarh. So plant sciences were always strong ,animal portions used to scare me.

What was the difference in preparation from the early days to just a month before NET exam?

There were more mock tests that I went through in the last one month. No other major difference as such since I had my revisions strong since day 1 of my preparation.

What strategy did you follow on exam day?

I didn't study 3 days prior my exam at all. Kept myself cool and calm, had a hearty meal on exam day and solved question paper in a very controlled and careful manner leaving aside any fear or panic.

What was the roughest and the easiest section according to you?

I was not good in maths and calculations so found part A bit tough. Part B and C, I found easy.

How did your family support you and motivate you during the preparations?

All credit for what I achieved today, goes to my Parents and My husband. My in-laws have been very supportive always, they never discriminated between daughter and daughter-in-law. My grandmother used to daily bless me with good wishes and success in my preparation, whenever I used to see her.

Any takeaways for the future NET aspirants?

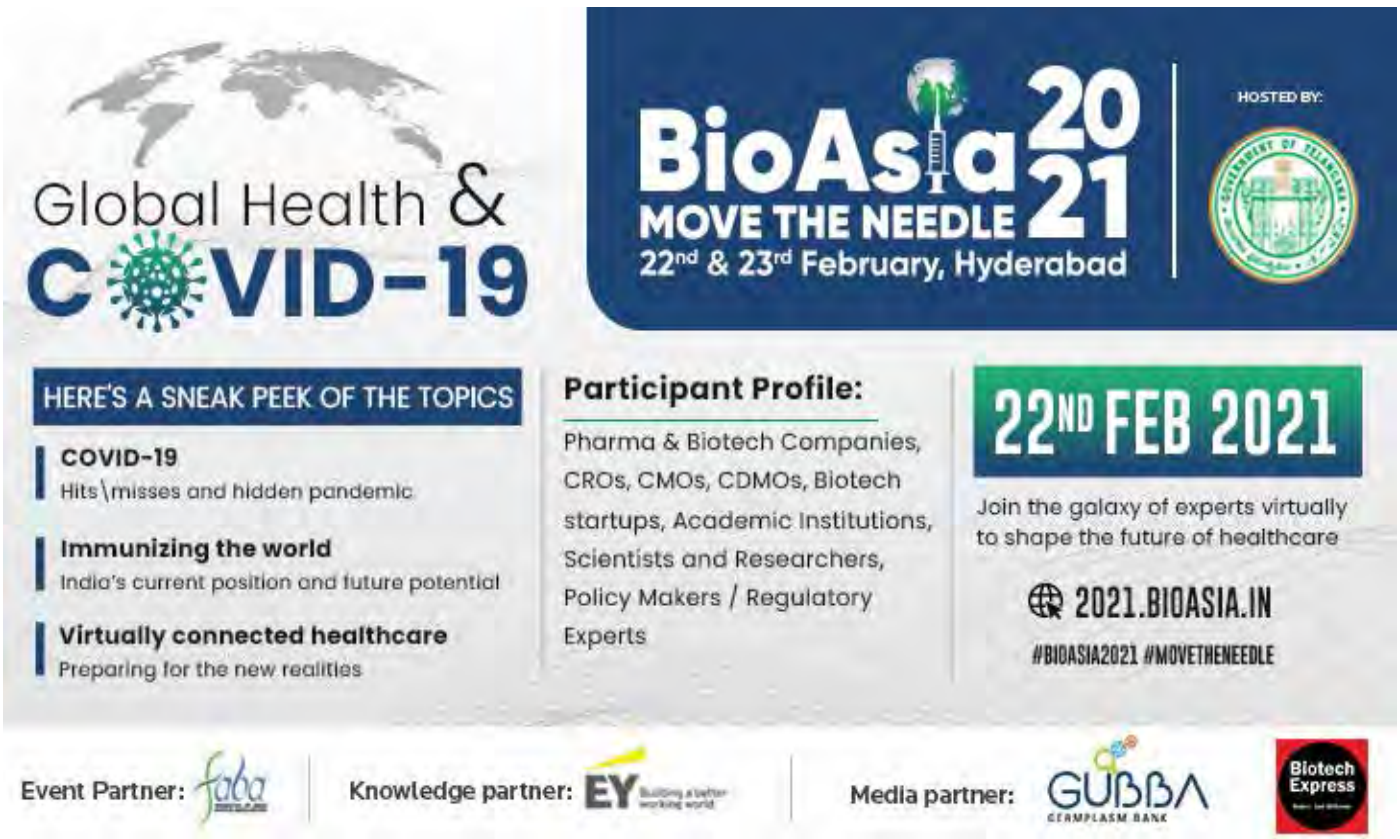
For future aspirants , I will say, just be a life science student in your learning irrespective of your background or stream of specialisation, be it botany/ zoology/biochemistry/ Biotechnology, be open to all topics in syllabus leaving aside any kind of biases.

Press Release - Event

BioAsia 2021 to focus on COVID-19 & Medtech

The 18th edition of BioAsia will be conducted virtually from February 22 to 23, 2020. Minister for Industries and Commerce KT Rama Rao unveiled the logo, website, and theme - Move the Needle - for the event.

"BioAsia, which is the State's flagship event, has emerged as an important global meeting to deliberate on the opportunities, challenges, and solutions for the Life Sciences sector," he said. "With the theme



'Move the Needle,' the event will provide a platform to deliberate on topics of paramount importance, essentially centered around dealing with Covid-19, preparing for new realities of healthcare, and much more. The Life Sciences Advisory Committee of the State will spearhead and advise on the conduct of the event," said Principal Secretary, IT and Industries, Jayesh Ranjan.

One of the sessions will also focus on the prospects of Medical Technologies becoming the next big opportunity for India that can accelerate the journey for the country from primarily being an importer to becoming a large-scale exporter, thanks to India's proven skill to innovate on frugal budgets, as evidenced by innovative Covid-19 diagnostic solutions.

The CEO conclave will deliberate on supply chain resilience, innovation and research, and access to innovative medicines, amongst others.

"Today Telangana is seen as one of the top life sciences destinations in the world. Over the years, BioAsia has played a critical part in uniting the worldwide business pioneers, scientists, policymakers, academia, and investors," Jayesh Ranjan, IAS, Principal Secretary, Industries & Commerce Dept., Government of Telangana, said.

Over the course of 17 years, the event has witnessed participation from over 20,000 leaders representing over 93 countries. Shakthi Nagappan, CEO of BioAsia and Director (Life Sciences), Government of Telangana, said, "Going virtual, the 2021 event will have a wider global reach and we are anticipating participation of about 30,000 Life Sciences professionals from around the world."

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Guest Article

Intensification of biokinetics of enzymes using ultrasound assisted methods: A critical review

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Abstract

The use of low intensity ultrasound has gotten surprising consideration over the last decade as a method for enhancing the catalytic activity of enzyme.Ultrasounds have the potential to significantly influence the activity of the enzymatic processes, provided that the energy input is not too high to inactivate the enzyme.By providing the variation in parameters, various physical and chemical effects can be attained that can enhance the enzymatic reaction. Ultrasonic reactors are known for their application in bioprocesses.However, the potential of their applications is still limited broadly due to the lack of proper information about their operational and performance parameters.In this review, the detailed information aboutultrasonic reactorsis provided by definingthe different types of reactors, number and position of ultrasonic transducers. Also, it includes mechanism of intensification and influence of ultrasonic parameters (intensity, duty cycle and frequency) and enzymatic factors (enzyme concentration, temperature and pH) on the catalytic activity of enzyme during ultrasound treatment.

Keywords: Ultrasound, Ultrasonic reactors, Enzyme kinetic, Enzymatic reaction, Sonochemical reaction

Introduction

The rapid growth in biotechnology is continually attracting new strategies and solutions for further advancement of bioprocess performances. Ultrasound has gotten surprising consideration over the last decade as a rapid method for enhancing the efficiency of bioprocesses [1].Ultrasonication is a branch of acoustics that can be applied to solids, liquids and gases at frequencies above the human hearing range. Ultrasound is defined as a sound wave having a frequency that exceeds the human ear's hearing limit (20 kHz). There are two major types of ultrasound i.e., low & high intensity. High intensity ultrasound uses high power (> $1Wcm^{-2}$) and low frequency (<0.1MHz) whereas low intensity ultrasound uses low power (< $0.1Wcm^{-2}$) and high frequency (0.1 to 100MHz)[2].

Ultrasound waves consist of a cyclic succession of expansion (rarefaction) and compression phases imparted by mechanical vibration. Compression cycles exert a positive pressure and push the liquid molecules together, while expansion cycles exert a negative pressure and pull the molecules apart. This causes cavitation and bubble collapse process.In the presence of the small solid surfaces (composite reactions), the collapse of bubbles near the solid surface leads to formation of microjets which improve the mass transfer and speed up the transport process. For the time being cavitation bubble collapse, the temperature and pressure inside the bubble reach greater than 5000 K and 1000 atm[3].Ultrasounds havethe potential to influence the activity of the enzymatic reaction, if the energy input is not high enough to inactivate the enzyme. Ultrasounds (US) having frequencies ranging from 20 kHz to 5 MHz are a type of mechanical energy which do not shows ionizing radiation properties[4]. Earlier, ultrasound having frequency above 30 kHz has been used as a method of enzyme inactivation to prevent the nutritive value of fruits and vegetables from undesirable effects (browning and off flavour) but recently, it has been found that activity of enzyme can be enhanced under milder condition of ultrasound irradiation. Enzymes are very sensitive to ultrasound treatment. An enzyme's catalytic activity is affected due to the continuous generation of waves and cavitation bubbles that leads to alteration in the loop and domain regions of enzyme[1].

Ultrasonic reactor is a system used for production of ultrasound. They are employed for various applications because of its special features. The occurrence of cavitation and acoustic streaming is the most important feature of ultrasonic reactors.Acoustic streaming causes physical effects and also enhances chemical processing limited by mass transfer. Sonochemical reactors are applied in various chemical and physical processes such as biotechnology,chemical synthesis,wastewater treatment, polymers degradation,wastewatertreatment, extraction, emulsification, crystallization, petrochemical industriesandleaching, etc.These reactors are very sensitive and unresistant to operational parameters. The proper knowledge and understanding on physical and chemical phenomenais required to control the operational parameters[5].

Over the past years,it has been found lots of review papers on application of ultrasound in chemical engineering, textile engineering, medicine, etc. However, very few review literatures have given attention on use of ultrasound in bioprocess and biotechnology.A considerable overview of the manner in which ultrasound affects biotechnological process was published by Sinisterra(1992) in his review "Application of ultrasound to biotechnology ". However, due to unavailability of much information at that time, the reviewer has presented a number of unpublished examples of his own research[6].In 2003, Chisti reviewed on the

reactions catalyzed by live cells using ultrasound and concentrated totally on enhancing effect of ultrasonic waves on live biological system and the design requirements for ultrasonic reactors[7]. Rokhina et al. gave a review on the use of low frequency ultrasound in biotechnology and focused mainly in areas where sonochemistry can be profitably connected with biotechnology[2].Recently, a mini review of the ultrasound assisted intensification of enzyme activityhas been reviewed (Nadar et al., 2017). The authors have presented an overview of influence of ultrasonic parameters on enzyme activity and techniques for immobilization of ultrasound irradiated enzyme[1].

The present review article will provide a deep analysis of factors and recent development associated to intensification of enzymatic reaction using ultrasound. Also, it will briefly discuss the mechanism of intensification of enzymatic activity and in-depth knowledge about ultrasonic reactors and their types. At last, ultrasonic and enzymatic factors that affect the enzyme activity will be discussed. This review will provide all the aspects related to intensification of different enzymes at one platform. It will be advantageous in bioprocesses such as food processing, enzymatic conversions, chemical synthesis using enzyme and for the research scholar whoever going to start their project on intensification of enzymatic activity using ultrasound.

Mechanism of intensification of enzymatic reaction using ultrasound

Introduction of ultrasound in liquid medium results in the generation of bubbles followed by collapse events. This event is termed as acoustic cavitation. The process of cavitation is represented in figure 1. The collapse of bubbles leads to formation of microjets which improve the mass transfer and speed up the transport of bulky enzyme molecule towards the solid or liquid interface where the real enzymatic reaction take place[8]. Ultrasound also changes the secondary structure of enzyme molecules that affects the enzyme activity. A study conducted on β-D- glucosidase showed the increase in α-helices and decrease in β-folds and asymmetrical β-fold of β-D-Glucosidase on ultrasound application results in rapid activation of enzyme[9]. Moreover,cavitation creates a hydrodynamic shear force in the liquid medium due to the quick breakdown of microbubbles, which helps in the deterioration of large materials into small particles, in this manner fundamentally expanding the surface zone for enzymatic attack.

During sonication, formation of free radicals such as atomic hydrogen and hydroxyl group due to sonolysis of water, superoxides and hydrogen peroxide also takes place. These free radicalsinteract with amino acid residues of the enzymes and damages the complex structures of an enzyme. However, the probability of enzyme molecules to interact with these free radicals is very low.Ultrasonic shockwaves produced due to sudden collapse of microbubbles alsostabilizes the enzyme by preventing the agglomeration of enzyme in solution[10].

Ultrasonic reactors for intensification of enzymatic reaction

Introduction: It isa system that has capability to transform electrical energy into ultrasonic vibrations. Generator, transducer and the application system are the major parts of ultrasonic reactor. Generator is the source of energy and the transducers converts the

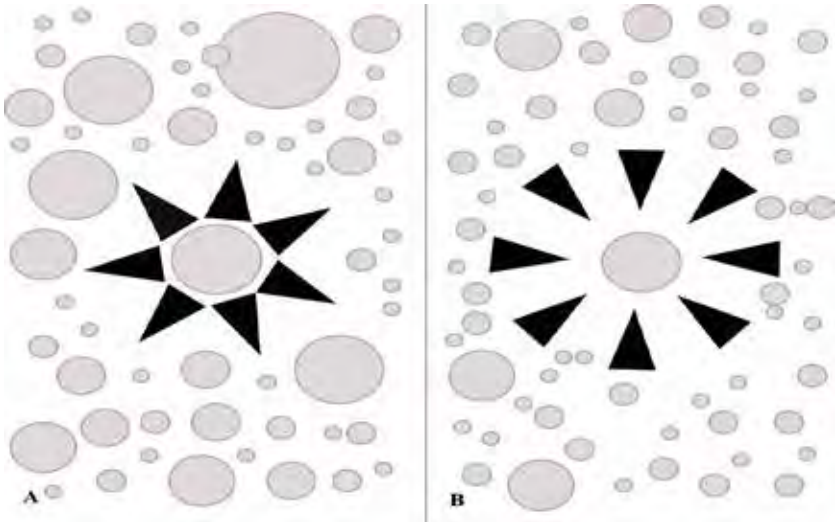


Fig. 1. Cavitation bubble formation. [A] Rarefaction [B] Compression[11]

energy produced by generator into mechanical energy in the form of vibrations[12].Magneto-strictive and piezoelectric transducers are most common type of transducers used in ultrasonic reactors. Magneto-strictive transducers are made from high strength metallic alloys and they are very stable, consistent and resistant to degradation. However, piezoelectric transducers are most commonly used, because of their high energy transfer efficiency than magneto-strictive transducers[10]. Reactor efficiency can be enhanced by choosing an appropriate type of transducer and having sufficient knowledge about number of transducers and their position in the reactor.Use of multiple transducers in the reactor helps to create a uniform distribution. Multiple transducers also provide better control of hydrodynamic conditions and mixing and the ability to use multiple frequencies. The use of ultrasonic waves always heats the solution and reactor during use. Therefore, the cooling of the system should also be carefully planned[13].

Types of ultrasonic reactors: Ultrasonic horns andultrasonic baths are the most common type of ultrasonic reactor used for enzymatic intensification reactions at laboratory scale. In the ultrasonic horn reactor, the transmitting element which submerges in the liquid medium consists of a horn linked to the transducer. Ultrasonic horn is a immersion type of reactor in which the ultrasonic waves aredirectly transmitted into the medium by vibrating horn[14]. Cavitational effects are very high close to the vibrating horn and decreases exponentially on moving away from the vibrating surface. The efficiency of horn type reactors is very low for large scale operations as compared to reactors based on multiple transducers. Additionally, erosion of horn tip due to high power applied to the horn and particle peeling increases the chances of stress induced fatigue failure[15].However, certain modifications are made in the shape and position of horn by some researchers to increase the sonochemical yield. Barbell-shaped horn,Donut shaped ultrasonic horn,Concentrator horn, Telsonic horn are the examples of modified form of ultrasonic horn. However, they are not powerful enough for scale up prospects because their capacity for transmission of irradiation into the large tank volume seems slightly

weak[10]. Horns can also be used longitudinally in the vessel for different applications. The longitudinal horns usually have higher surface area of irradiation in the medium and the magnitude of energy efficiency in this type of ultrasonic is higher than the conventional one. Moreover, the broad irradiation area of longitudinal ultrasonic horns leads to uniform distribution of cavitational activity in the whole reactor volume which can be more beneficial in pilot scale in comparison with simple ultrasonic horns [13].

Ultrasonic baths are also commonly usedultrasonic reactors in which transducers are attached at the bottom of the reactor and ultrasound irradiations are transmitted into the system indirectly.Cavitational intensity of ultrasonic baths are less as compared to ultrasonic horns because they are indirect irradiation-based ultrasonic reactors. They are generally applied where specific ultrasonic intensity is not required. The maximum operating capacity of the ultrasonic bath is about 3 litres, but baths with higher capacity (up to 1000 litre) is also possible with some modification in terms of larger number of transducers in different configurations. Moreover, ultrasonic bath-type of reactors are suitable for laboratory to large-scale operations, but there is a problem on the number of transducers that can be attached in a system for a large-scale operation[5]. Dual frequency flow cell and triple-frequency flow-cell-type reactors are the reactors based on the use of multiple transducers. They are very much effective in continuous operations.These reactors produce a beat frequency inside a chamber that continually oscillates within reactor chamber and ensures constant processing.There are two sets of magneto-strictivetransducers (i.e.,three in each side) attached on the two opposite walls in dual frequency flow cell. In case of triple frequency flow cell, there are three transducers attached in each set per side and having equal power dissipation per side. The use of multiple transducers is helpful in concentrating the ultrasonic waves towards the central zone of vessel[5,15].

Factors affecting enzymatic reactions

Ultrasonic frequency: The frequency of an ultrasound is an important influential factor for enzymatic reactions. The ultrasounds frequency has a direct influence on the cavitation bubble collapse. Ultrasonic irradiation of enzyme at optimum frequency causes conformational changesin protein structure of enzyme which leads to increment in enzyme activity. A research was conducted on the effect of ultrasound frequency on cellulase activity. The researchers have found an increment in catalytic activity of immobilized cellulose by 6.56, 14.79, 17.85 and 10.45% at frequencies of 18, 20, 24 and 26 kHz, respectively. The increment in catalytic activity was due to the ability of ultrasound to increase the surface area of immobilized enzyme molecules. However, a decrement of 1.02% at 29 kHz was found in catalytic activity of enzyme molecule due to rapid collapse of cavitation bubbles at higher frequencies which leads formation of excessive heat[16].In

Type of reactor	Cavitational yield (mol/W)
Ultrasonic horn	0.0005
Ultrasonic bath	0.01
Dual frequency flow cell	0.011
Triple frequency flow cell	0.018
Longitudinally horn reactor	0.077

Table 1. Comparison of cavitational yield in ultrasonic reactors[5]

another research, the effect of ultrasound frequency on alkaline protease catalytic activity was analyzed by exposing enzyme at three different frequencies 40, 80, and 100 kHz. The yields under ultrasound were better than that of shaking and at 80 kHz, highest yield was found.Thus, ultrasound irradiation with optimum frequency is needed during treating enzyme to bring better results[17].

Ultrasonic power or intensity: Ultrasonic intensity is an important factor which plays major role in enhancing or inhibitory effects of ultrasound on enzyme activity.Yujing et al. (2019) conducted an experiment on the effect of ultrasonic intensity on β-d-glucosidase catalytic activity and found that the activity was increased with increasing ultrasonic intensity upto 181.53 W/cm^2. However, its activity started decreasing after 181.53 W/cm^2. The results showed that use of low intensity ultrasound creates cavitation and mechanical oscillation which leads to conformational changes in enzyme and increase its contact with the substrate. Under the condition of high intensity ultrasound, inhibition of enzyme activity occurs due to interaction of generated free radicals with protein backbone[9]. In another study, the effect of ultrasound intensity on cellulase activity was explored by irradiating an enzyme to various intensities and maximum activity was observed at 17.33W/cm^2. The explanation for this is, low intensity ultrasound breaks the weak interactions such as hydrogen bonds or Van der Waals forces which bring the conformational alteration in active site of enzyme[18].

Duty cycle: Duty cycle is another important parameter of ultrasound that affects the enzyme activity. Theuse of a duty cycle is more economical than continuous energy application. It keeps the temperature of the reaction sample at optimum levels and protects the enzyme from denaturation. It also helps to control irradiation time of ultrasound on enzyme and reduction in energy consumption[19].A study was conducted on β-d-glucosidase for evaluation of effect of duty cycle on its catalytic activity. The results indicated that the activity was enhanced when duty cycle was between 33.33% to 40%. However, a slight decrease in yield was found when duty cycle ranged from 40% to 100%. The reason for the decrease in yield at higher duty cycle was due to extensive cavitation which affect the active conformation of enzyme. On the other side, a lower duty cycle seems to be a better choice for the activation of enzyme[9]. In another study on lipase at different duty cycle showed the maximum enzyme activity at 66.67%. The reason for maximum activity at 66.67% might be due to proper application of impulsive forces on enzyme was given by authors[20]

Concentration of enzyme: Concentration of enzyme plays a critical role in analyzing the effects of ultrasound irradiation. At very low concentration of enzyme, the probability of enzyme molecules to effectively interact with micro streams generated due to acoustic cavitation is very less. Conversely, above the optimum concentration,excessive enzyme molecules impede the energy-transfer process, thereby decreasing the available energy for cavitational phenomenon. An excess enzyme molecule also increases the probability of forming aggregates of enzymes due to cavitation, which results in a lower degree of intensification. Enzyme kinetics also indicated the decrease in rate of reaction due to competition for substrate by enzyme molecules at high concentration of enzyme[20].

pH and temperature:pH and temperature both plays an important role in determining the effects of ultra-

sound irradiation. Higher and lower pH and temperature can lead to partial or complete inhibition of enzyme catalytic activity. Wei-ming Wang et al. (2012) investigated the effect of pH on amylase activity applied for desizing of cotton fabric. The authors have found that desizing percentage values significantly increased with pH value increased upto 6. However, antagonistic effectshave been found on catalytic activity of amylase abovepH value of 6[21].Souza et al. studied the effects of temperature on the activityof alpha amylase on ultrasound treatment. They found three times increase in catalytic activity of alpha amylase for temperature increase upto 40% on ultrasonic irradiation. The results indicated that the cavitation ishigher at lower temperature and optimum temperature range is required to break strong interaction such as hydrogen bonding, dipole attractions and Vander Waal forces between the substrate and active sites on the enzyme[22].

Conclusion

In summary, Low intensity ultrasound can be used as a tool for intensification of enzymatic reaction. It is very effective in activation of enzyme by changing the structural conformation of active site and also effective in improving the stability of enzyme and kinetic factors. Cavitation

phenomenon from ultrasound is required to attain higher reaction rates. Choosing an appropriate reactor is a critical task for specific enzymatic reactions. An ultrasonic reactor appears to be very effective for enzymatic intensification reactions.It is economically beneficial duetotheirspecialfeaturessuchas acoustic cavitationandacousticsstreaming.Parameters such as ultrasonic frequency, ultrasonic intensity, duty cycle, temperature, pH and treatment time determine the activation or inhibition of enzyme. Controlling these parameters and maintain uniform distribution of cavitational activity in reactor is one of the most important challenges in scale up ultrasonic reactors. There is lack of proper information about enzyme working environment. Therefore, it is necessary to collect complete information on ultrasonic effects under various experimental conditions. It will be helpful in developing mathematical model and easy prediction of changes in the efficiency of the process.

Acknowledgement

We wish to show my appreciation to Institute of Chemical Technology, Mumbai for providing us the right environment to write this review.

References

1. Nadar, S. S., & Rathod, V. K. (2017). Ultrasound assisted intensification of enzyme activity and its properties: a mini-review. *World Journal of Microbiology and Biotechnology*, *33*(9), 170.
2. Rokhina, E. V., Lens, P., &Virkutyte, J. (2009). Low-frequency ultrasound in biotechnology: state of the art. *Trends in biotechnology*, *27*(5), 298-306.
3. Bhangu, S. K., &Ashokkumar, M. (2017). Theory of sonochemistry. In *Sonochemistry* (pp. 1-28). Springer, Cham.
4. Vartolomei, A., Calinescu, I., Vinatoru, M., &Gavrila, A. I. (2019). Intensification of the Enzymatic Esterification Process by Ultrasounds. *REVISTA DE CHIMIE*, *70*(1), 41-44.
5. Asgharzadehahmadi, S., Raman, A. A. A., Parthasarathy, R., &Sajjadi, B. (2016). Sonochemical reactors: Review on features, advantages and limitations. *Renewable and Sustainable Energy Reviews*, *63*, 302-314.

6. Sinisterra, J. V. (1992). Application of ultrasound to biotechnology: an overview. *Ultrasonics*, *30*(3), 180-185.

7. Chisti, Y. (2003). Sonobioreactors: using ultrasound for enhanced microbial productivity. *TRENDS in Biotechnology*, *21*(2), 89-93.

8. Yachmenev, V. G., Bertoniere, N. R., & Blanchard, E. J. (2002). Intensification of the bio-processing of cotton textiles by combined enzyme/ultrasound treatment. *Journal of Chemical Technology & Biotechnology*, *77*(5), 559-567.

9. Sun, Y., Zeng, L., Xue, Y., Yang, T., Cheng, Z., & Sun, P. (2019). Effects of power ultrasound on the activity and structure of β-D-glucosidase with potentially aroma-enhancing capability. *Food science & nutrition*, *7*(6), 2043-2049.

10. Subhedar, P. B., &Gogate, P. R. (2013). Intensification of enzymatic hydrolysis of lignocellulose using ultrasound for efficient bioethanol production: a review. *Industrial &Engineering Chemistry Research*, *52*(34), 11816-11828.

11. Islam, M. N., Zhang, M., & Adhikari, B. (2014). The inactivation of enzymes by ultrasound—a review of potential mechanisms. *Food Reviews International*, *30*(1), 1-21.

12. Cárcel, J. A., García-Pérez, J. V., Benedito, J., &Mulet, A. (2012). Food process innovation through new technologies: Use of ultrasound. *Journal of Food Engineering*, *110*(2), 200-207.

13. Gogate, P. R., & Patil, P. N. (2017). Sonochemical reactors. In *Sonochemistry* (pp. 255-281). Springer, Cham

14. Chemat, F., & Khan, M. K. (2011). Applications of ultrasound in food technology: processing, preservation and extraction. *Ultrasonics sonochemistry*, *18*(4), 813-835

15. Gogate, P. R., &Kabadi, A. M. (2009). A review of applications of cavitation in biochemical engineering/biotechnology. *Biochemical Engineering Journal*, *44*(1), 60-72

16. Wang Z, Lin X, Li P, Zhang J, Wang S, Ma H (2012) Effects of low intensity ultrasound on cellulase pretreatment. Bioresour Technol 117:222–227

17. Xiao, Y., Yang, L., Mao, P., Zhao, Z., & Lin, X. (2011). Ultrasound-promoted enzymatic synthesis of troxerutin esters in nonaqueous solvents. *Ultrasonics sonochemistry*, *18*(1), 303-309.

18. Subhedar, P. B., &Gogate, P. R. (2014). Enhancing the activity of cellulase enzyme using ultrasonic irradiations. *Journal of Molecular Catalysis B: Enzymatic*, *101*, 108-114.

19. Freitas, V. O. D., Matte, C. R., Poppe, J. K., Rodrigues, R. C., &Ayub, M. A. (2019). Ultrasound-assisted transesterification of soybean oil using combi-lipase biocatalysts. *Brazilian Journal of Chemical Engineering*, *36*(2), 995-1005.

20. Jadhav SH, Gogate PR (2014) Intensification in the activity of lipase enzyme using ultrasonic irradiation and stability studies. Ind Eng Chem Res 53:1377–1385

21. Wang, W., Yu, B., & Zhong, C. (2012). Use of ultrasonic energy in the enzymatic desizing of cotton fabric. *Journal of Cleaner Production*, *33*, 179-182.

22. Souza M, Mezadri ET, Zimmerman E et al (2013) Evaluation of activity of a commercial amylase under ultrasound-assisted irradiation. UltrasonSonochem 20:89–94

NATIONAL VIRTUAL CONFERENCE

ON

"GENOMICS TO PHENOMICS: A NEW HORIZON IN PLANT SCIENCE RESEARCH" (NVC-2021)

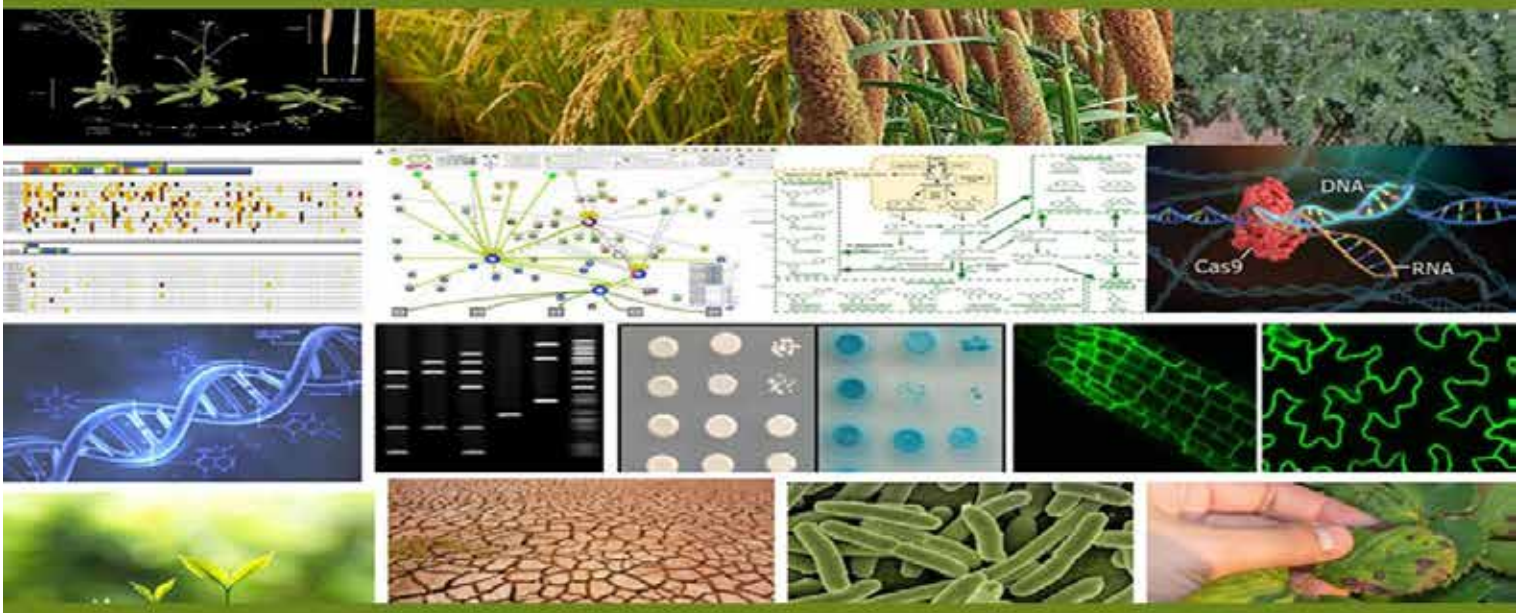
& BIOINFORMATICS E-WORKSHOP

ON

"SURGE ON GENOMICS DATASETS: MICROBES TO PLANTS"

Organised by : Department of Botany, University of Calcutta

(February 28th - 1st March, 2021)



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Honourable Vice Chancellor
Biswa Bangla University, Bolpur, West Bengal

Meet our Speakers

Prof. Prabodh Trivedi
Director, CSIR-CIMAP

Dr. Manoj Prasad
NIPGR

Dr. Subhadeep Chatterjee
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(Bioinformatics Workshop Coordinator)

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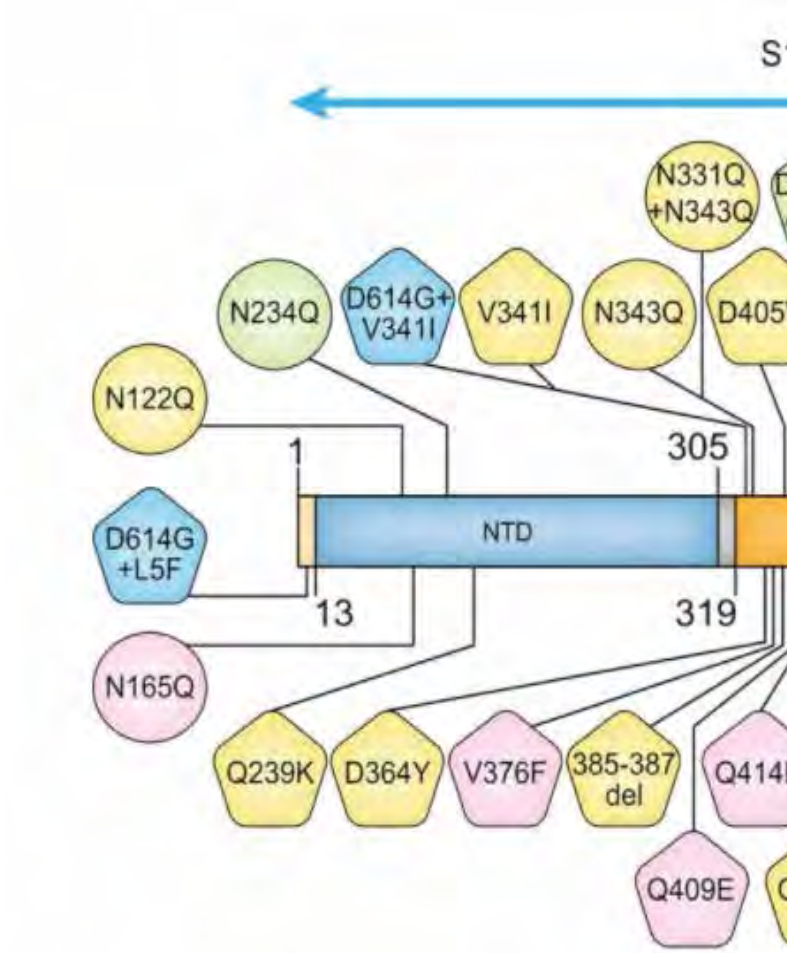
Top highlights of
Biotech Industry and Govt



List of SARS-CoV-2 Variants

FEBRUARY 12, 2021

Viruses are continually evolving, and there is no exception for SARS-CoV-2. Many variants of SARS-CoV-2 have been reported worldwide throughout this pandemic. Experts believe that the variants' specific patterns of mutations have the potential to impact their transmissibility, virulence, and/or ability to escape from the immune system.

Few notable variants of SARS-CoV-2 are discussed here:

B.1.1.7 Lineage
This set of coronaviruses emerged in Britain in December, where it was called Variant of Concern 202012/01; it is also referred to as 20I/501Y. V1, or B. 1.1.7. Coronaviruses from the B. 1.1.7 lineage are believed to be about 50% more contagious due to several mutations in its spike protein. Presently, B.1.1.7 has been reported in more than 70 countries. The CDC has cautioned that B. 1.1.7 could become the primary cause of all cases in the USA by March.

B.1.351 Lineage
20H/501Y. V2, also known as 501.V2 (formerly 20C/501Y.V2) from the B.1.351 lineage of coronaviruses, was first reported in South Africa on 18 December 2020 and was detected in the United States in January. Since then, it has expanded to at least 24 nations.

P.1 Lineage
20J/501Y.V3 is from the P.1 lineage, a descendant of the larger B.1.1.28 lineage. This variant was first detected in Japan in individuals infected with P.1 on vacation to Brazil. The lineage arose in late 2020 in Manaus, Brazil. P.1 is a close relative of the B.1.351 lineage, and it has a few of the very identical mutations on the SARS-CoV-2 spike protein.

Lineage B.1.1.207
B.1.1.207 is the split from B.1.1.53, which was initially sequenced in August 2020 in the African Centre of

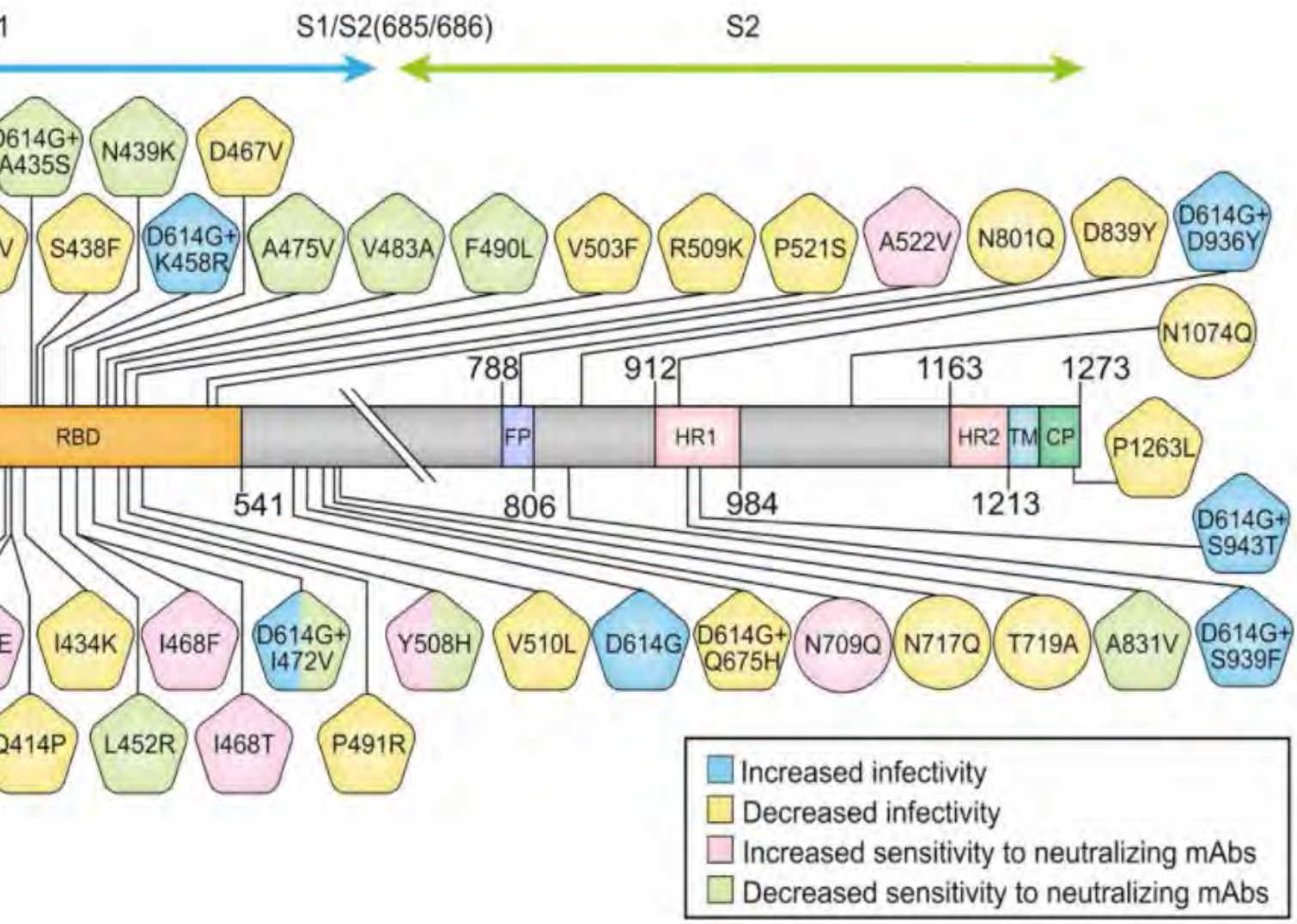


Image: Schematic illustration of amino acid changes in spike protein. Mutations yielding at least fourfold changes in infectivity and neutralizing reactivity to mAbs are shown in the figure. Source: https://www.nature.com/articles/s41392-020-00302-8

Excellence for Genomics of Infectious Diseases, Nigeria. This variant is predominantly found in the USA (89%), Mexico (3%), Ecuador (3%), UK (2%). Currently, no proof implies that B.1.1.207 has any impact on COVID-19 transmission or severity.

CAL.20C Variant

CAL.20C Variant was first detected in California at Cedars-Sinai Medical Center in July 2020 in 1 of 1,230 samples accumulated in Los Angeles. CAL.20C spans the B.1.427 and B.1.429 lineages. It has multiple mutations in the S protein. Yet, it's not proved whether it is more contagious or not. This variant surged in late 2020.

Cluster 5

Cluster 5, also called ΔFVI-spike by the Danish State Serum Institute, was first uncovered in Northern Jutland, Denmark, in early November 2020. It is thought to have actually spread from minks to humans through mink farms. According to the WHO, cluster 5 has a reasonably lowered sensitivity to neutralizing antibodies.

COH.20G/501Y

COH.20G/501Y was initially reported by the Columbus-based Ohio State University Wexner Medical Center and OSU College of Medicine.

S Q677H variant

The Midwest variant or S Q677H variant – the Viruses containing the S Q677H mutation have recently become prevalent in samples assessed in December and January in Ohio. There is no evidence of modified transmissibility, virulence, and/or immune evasion reported as of now.

India Budget 2021 – Healthcare and research

FEBRUARY 2, 2021

India's finance minister, Smt. Nirmala Sitharaman, presented the country's budget Monday for the fiscal year that begins April 1 and ends March 31, 2022.

In her speech to Parliament, she proposed more than doubling India's health-care and wellbeing spending to 2.2 trillion rupees ($30.1 billion). That includes a new federal scheme with an outlay of 641 billion rupees over six years to develop the country's capacity for primary, secondary and tertiary care as well as to strengthen national institutions and create new ones to detect and cure new diseases, Sitharaman said.

The budget will allocate 350 billion rupees for COVID-19 vaccines and the government is committed to providing further funds if required, according to the finance minister.

India last month rolled out a mass immunization program that aims to inoculate 300 million people in its first stage, most of them frontline workers and those above 50 or in high-risk groups. The country has the second-highest number of COVID-19 cases in the world, with more than 10.7 million reported infections. The healthcare funding is done for the following:

A new federal scheme with an outlay of 641 billion rupees over six years to develop the country's capacity for primary, secondary and tertiary care.

Support for 17,788 rural and 11,024 urban health and wellness centers as well as strengthening the National Center for Disease Control.

A program to provide clean water in urban areas as well as liquid waste management over five years and allocated 2.87 trillion rupees.

Voluntary vehicle scrapping policy to phase out old vehicles that contribute to India's poor air quality.

She also earmarked ₹50,000 crore over five years for the creation of a National Research Foundation (NRF) — an umbrella body that is expected to fund research across a range of disciplines, from science and technology to humanities. Ms. Sitharaman had first announced such a foundation in her 2019 Budget speech after it was proposed in a draft of India's New Education Policy (NEP). "It [NRF] will ensure that the overall research ecosystem in the country is strengthened with a focus on identified national priority thrust areas."

The budget allocations for key science departments are:

The Ministry of Earth Sciences was budgeted ₹2,074 crore for 2020-21, but is expected to spend only ₹1,304 crore. This year it has been allotted ₹1,901 crore.

The Department of Science and Technology was budgeted ₹6,313 crore last year, but will likely spend ₹5,012 crore. It has been allotted ₹6,071 crore this year.

The Department of Scientific and Industrial Research was given ₹5,385 crore but its expenses are likely to be ₹4,251 crore. It has been given ₹5,241 crore.

The Department of Biotechnology has seen a hike in allotment and been given ₹3,502 crore. Last year, it spent ₹2,300 crore and was budgeted ₹2,786 crore.

The Budget also announced a National Language Translation Mission (NTLM) which will enable the wealth of governance-and-policy related knowledge on the Internet being made available in major Indian languages. And Deep Ocean Mission with a budget outlay of more than INR 4,000 crores, over five years has been announced. This Mission will cover deep ocean survey exploration and projects for the conservation of deep sea bio-diversity. Also, many of the cities in India have various research institutions, universities, and colleges supported by the Government of India. In 9 such cities, formal umbrella structures have been proposed in order to ensure that these institutions can have better synergy, while also retaining their internal autonomy. A Glue Grant will be set aside for this purpose. The Natural Language Translation Mission and Deep Ocean Mission are the national missions and the City Research and Innovation Clusters Project have been initiated from the Prime Minister's Science Technology Innovation Advisory Council.

Covaxin Neutralizes UK Variant Of COVID-19 in lab Setting: ICMR

FEBRUARY 1, 2021

Scientists at ICMR's National Institute of Virology (NIV) and Bharat Biotech have released a pre-print, non-peer-reviewed paper, which has found that when tested in a lab, neutralising antibodies produced by Covaxin have the ability to combat the mutant UK strain of the coronavirus.

Among the foremost concerns around the UK strain is that vaccines may not be able to perform as efficiently because of the mutations on the virus' surface.

"A comparable neutralization activity of the vaccinated individuals sera showed against UK-variant and the heterologous strain with similar efficiency, dispel the uncertainty of possible neutralization escape," says the paper, which was released on 26 January on the non-peer-reviewed site biorxiv.

Bharat Biotech's Covaxin was under the scanner earlier this year when it was given emergency use authorisation though it had not released any efficacy or phase three data.

Indian Council for Medical Research (ICMR) chief Balram Bhargava defended the approval in early January, saying Covaxin was more likely to protect against the UK strain, though there was no publicly released data to support the claim at the time.

The UK variant has 17 mutations, eight of which are found in the spike protein.

"Therefore, it appeared that the majority of the vaccine candidates, being either recombinant or specifically targeting the single epitope of original D614G ancestral spike sequence, might not be able to generate an efficient immune response against the new variants," reads the paper.

Bharat Biotech's Covaxin, on the other hand, is made of a whole inactivated virus, and is not based solely on the spike protein. The experiment was conducted in a laboratory, using the sera of 26 trial participants who had been vaccinated with Covaxin.

The antibodies of the vaccinated trial participants were used against three strains of the Covid-19 virus for the experiment — hCoV19/India/2020770, which was used by the NIV for the development of Covaxin, hCoV-19/India/2020Q111, a local strain that has been circulating in India, and the hCoV-19/India/20203522, the mutant UK strain.

"The median ratio of 50% neutralization of sera was found to be 0.8 when compared with hCoV-19/India/2020770 against mutant hCoV19/India/20203522 (UK strain), and 0.9 while compared with hCoV-19/India/2020Q111," reads the paper.

CCMB scientists find different variant of SARS-CoV-2 in India

JANUARY 28, 2021

Scientists at the CSIR-Centre for Cellular and Molecular Biology here have found prominently a different variant of SARS-CoV-2 in southern parts of India, a top official of the institute said.

Dr Rakesh Kumar Mishra, director of CCMB, said the different variant (N440K) appears to be milder than the existing one and the institute is stepping up research on it to ascertain its prevalence in the country. The findings came amid the concerns of a mutated variant of SARS-CoV-2 found in the UK.

"It is not a new variant that we found. It is N440K. It is a different variant. This is there for some time. ThisN440K was a very small number in September and October last year. Now it looks like it is getting a much bigger proportion.

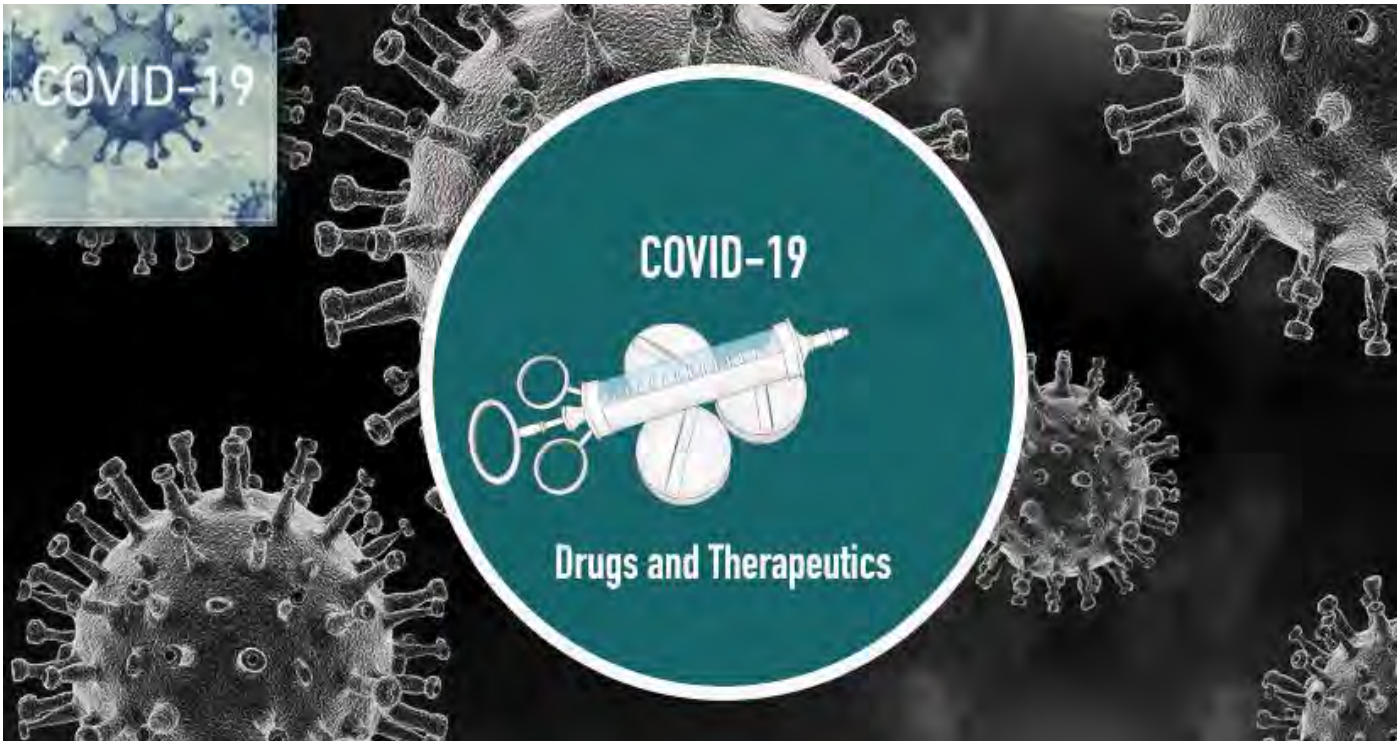
No symptoms issues with N440K," Dr Mishra told PTI.

"Either this (the different variant) has become normal or the earlier one became weaker. But certainly symptom wise if it is not equal, it (the different one) is milder. We don't have enough data as of now. We are accelerating… I think in coming days we will do large-scale sequencing," he explained.

He said the variant is seen in Telangana and Andhra Pradesh and other southern states and scientists have no sufficient data to prove its existence in other parts of the country.

Mishra said the CCMB did not see any increased number of cases or symptoms with this variant of the virus.

India has 30 COVID-19 vaccine candidates under development



JANUARY 27, 2021

Nearly 30 candidates for the COVID-19 vaccine are under development across the country, by industry and academia.

Being at the forefront of covid-19 vaccine development in the world, India, the second-most populous country in the world, is not only aiming to inoculate maximum number of its people against coronavirus but is also aggressively conducting research on decoding the SARS-CoV-2 virus.

The Vaccine Maitri Initiative has been launched in line with the principle of contributing to the healthcare needs of the global community and as announced by Prime Minister Narendra Modi during the UN Summit and Vaccine Summit. Free supplies of covid-19 vaccine have been sent to neighbouring countries including Bhutan, Maldives, Bangladesh, and Nepal.

Consignments are also being made available to Myanmar, Mauritius, and Seychelles. Vaccine supplies to Afghanistan and Sri Lanka are also being considered. Commercial supplies are also being considered for Brazil, Morocco, South Africa, and Saudi Arabia.

Covax is in discussion with many countries and decisions will depend on vaccine manufacturing capacities and availability. Under Vaccine Maitri, the DBT along with the Biotechnology Industry Research Assistance Council (BIRAC), is working closely with the ministry of external affairs and has launched the Partnerships for Accelerating Clinical Trials (PACT) programme for strengthening clinical trial capacity for covid-19 vaccine development in neighbouring and friendly countries.

The PACT initiative has two major components, facilitation of phase III clinical trials of Indian covid vaccines whereby phase III clinical trials of Covaxin in Bangladesh and Myanmar are under consideration, and training for strengthening clinical trial capacities.

The training is being organized to build capacities of the investigators, health workers, technicians, nurses and support staff from hospitals, community health centres, other health agencies, and field sites to gain knowledge of the processes for conduct of trials in compliance with International Conference on Harmonisation- Good Clinical Practise (ICH-GCP) guidelines.

Mission Covid Suraksha, has been launched by the DBT, to accelerate the indigenous covid-19 vaccine development efforts and bring the vaccines to market. Bharat Biotech's Covaxin and Serum Institute of India's Covishield have already been accorded emergency use authorization. In addition, five vaccine candidates are in various stages of clinical development. The DNA vaccine candidate by Zydus Cadila ZyCov-D and the Russian Sputnik V vaccine candidate are in Phase III clinical trials. The protein subunit vaccine candidate by Biological E is in the Phase I/II clinical trials stage of development. The mRNA Vaccine candidate by Gennova and the nasal single dose vaccine of Bharat Biotech have also been authorised for phase I trial.

Tatas may partner with Moderna to launch COVID-19 vaccine in India

JANUARY 25, 2021

Tata Medical and Diagnostics, the healthcare unit of the Tata Group, is reportedly in early talks with Moderna, an American biotechnology company, for a tie-up to roll out anti-coronavirus vaccine in India. It is worth noting that in November last year the Tata Group had launched a Covid-19 test kit that gives results in under an hour and as precise as the RT-PCR method.

Tata is likely to join hands with the Council of Scientific & Industrial Research (CSIR)—India's premier research organisation—to conduct clinical trials of Moderna's vaccine candidate in India.

It is worth mentioning here that foreign vaccine makers must carry out a bridging trial on the Indian population in the country before rolling out their products. More importantly, if the vaccines are approved abroad, foreign companies must conduct phase-3 trials with volunteers in India.

In January 2020, the Coalition for Epidemic Preparedness Innovations (CEPI)—a part of the COVAX facility of the World Health Organisation—provided funds to Moderna to develop its mRNA vaccine against the

coronavirus. Plus, the COVAX facility wants to equitably distribute 200 crore Covid-19 vaccines in low- and middle-income countries including India by the end of 2021.

In June 2020, the Mumbai-based coffee-to-cars conglomerate established Tata Medical & Diagnostics amid the coronavirus crisis and is ready to enter the country's Covid-19-led health requirements in the devices and formulations space.

Phase I Clinical Trial Data pertaining to Bharat Biotech COVAXIN BBV152 Finally Published

JANUARY 23, 2021

The Phase I trials of COVAXIN BBV152 inactivated vaccine prepared against SARS-CoV-2 was conducted between 13th to 30th July 2020. It involved 375 participants, of which 100 each were assigned to three different groups that were administered different vaccine doses. The control group was formed by 75 participants. The trial took place at 11 hospitals across nine states in India and the participants were aged between 18 to 55 years old.

The participants were initially screened for COVID-19 through the gold-standard RT-PCR test. The original pool comprised 827 people but those with a temperature above 37 degrees celsius and a known allergy to any vaccine component were excluded.

The three vaccine formulations administered were "3 µg with Algel-IMDG, 6 µg with Algel-IMDG, or 6 µg with Algel". Algel-IMDG, or chemosorbed imidazoquinoline onto the aluminum hydroxide gel, is the adjuvant (toll-like receptor (TLR) 7/8 agonist) which is used with the vaccine in order to boost immune response. The vaccine is supposed to induce T-helper-1 cell (Th1) responses. According to the study, adverse events were reported in 17 participants in the first group, 21 in the second group, 14 in the third group and 10 in the control group. There was only one serious adverse event which had been reported in the third group that was administered 6 µg of the vaccine with Algel, a case of viral pneumonitis, which the researchers ascertained was unrelated to the vaccine.

The Lancet study concluded "BBV152 led to tolerable safety outcomes and enhanced immune responses." Both the Algel-IMDG formulations were selected for Phase II immunogenicity trials.

India received 2.5 billion dollars from World Bank to fight COVID-19

JANUARY 22, 2021

India has received three loans worth $2.5 billion to fight the deadly coronavirus disease outbreak, the government said on Tuesday. The loans were provided under three classifications – health, social protection and economic stimulus, union minister Anurag Thakur told the Rajya Sabha in September 2020.

Stating that all Indian states and union territories have benefitted from the loan, Thakur told the Rajya Sabha that the first loan was signed on April 3, shortly after India announced a nationwide lockdown to aid the virus related health measures.

The first loan was extended by the World Bank to partly finance India's measures to prevent, detect and respond to the threat posed by the disease outbreak, in addition to strengthening national machinery for public health preparedness. Out of the total $1 billion, 502.5 million stands disbursed.

Thakur added that the second instalment of World Bank's financial assistance to India came on May 15 and has been fully disbursed. The reply submitted in Rajya Sabha stated, "The second loan relating to social protection measures worth $750 million was signed on 15th May, 2020 as budgetary support to Government of India for 'Accelerating India's COVID-19 Social Protection Response Programme' to support relief measures to beneficiaries under Pradhan Mantri Garib Kalyan Package (PMGKP)."

The third loan aimed at boosting economic stimulus worth $750 million was signed on July 6, 2020 as budgetary support to Government of Indian government in order to support MSMEs under Aatma Nirbhar Bharat Package (ANBP).

Biotech Industry News

Merck's CEO Ken Frazier Steps Down After 30 Years

FEBRUARY **04, 2021**

Merck Chief Executive Officer Kenneth C. Frazier is stepping down from his role atop the helm of the pharma giant on June 30 after nearly 30 years with the company. He will be replaced by Robert M. Davis, Merck's chief financial officer and head of global services.

Frazier is one of the highest-profile African American CEOs in not only the pharma industry, but also the United States. He was the first African-American to lead a Fortune 500 company. He has been with Merck since 1992 when he joined the company as vice president, general counsel and secretary of the Astra Merck group.

Over the course of his career, Frazier has held multiple leadership roles within the company. He became CEO in 2011. Although Frazier is stepping down as CEO, he will serve as executive chairman of the board of directors.

In a brief statement issued this morning, Frazier called it a privilege to serve as Merck's CEO. He also praised the "dedicated and talented employees and management team" at the company. During his tenure at the helm, the company has seen one of its cancer assets, the checkpoint inhibitor Keytruda, become one of the most-prescribed cancer drugs. Keytruda is poised to become to become the top-selling drug in the world in the next few years.

In 2017, Frazier made headlines when he resigned from a presidential manufacturing council following Donald Trump's failure to adequately condemn white supremacists in the aftermath of the violence in Charlottesville, VA.

In 2018, Frazier was named one of the World's Greatest Leaders by Fortune Magazine and also was named to the Time 100 Most Influential People. In 2019, he became the first recipient of the Forbes Lifetime Achievement Award for Healthcare.

Court Rules against Amgen PCSK9 Patent Claims against Sanofi and Regeneron

FEBRUARY **12, 2021**

A long-running court battle over PCSK9 antibodies between Amgen and Sanofi and Regeneron has come to an end, for now at least. Amgen lost its bid to uphold patent claims for its cholesterol drug, Repatha against the rival drug Praluent, developed by Sanofi and Regeneron.

The U.S. Court of Appeals for the Federal Circuit upheld a 2019 decision from a lower federal court that invalidated Amgen's asserted patent claims for PCSK9 (proprotein convertase subtilisin/kexin type 9) antibodies. Those claims, the court said, are invalid based on lack of enablement.

In a joint statement, Sanofi and Regeneron said they have successfully invalidated all five of Amgen's asserted claims relevant to Praluent (alirocumab). Thursday's decision follows the October 2020 ruling by the European Patent Office's (EPO) Technical Board of Appeal that also invalidated certain functional claims of Amgen's European patent directed to PCSK9 antibodies.

While the PCSK9 inhibitors are capable of significantly reducing the levels of bad cholesterol in people, neither Repatha nor Praluent has financially delivered in the market in the manner the companies and analysts hoped for when the drugs were approved. Primarily, the medications have largely been used for patients who have extremely high cholesterol levels that can't be modified by diet, exercise and statin medications.

Dana-Farber and Deerfield Join $130 Million Collab

Feb 08, 2021

In a historical move, healthcare investor giant Deerfield Management has entered a second partnership with one of its academic collaborators. Investing up to $130 million over the next ten years into Dana-Farber Cancer Institute, the collaboration hopes to advance development of new therapeutics and diagnostic tools for cancer patients.

The first partnership was an $80 million investment to create the Center for Protein Degradation at Dana-Farber.

This new funding will create a translational research partnership to launch Riverway Discoveries.

"Translational funding in biomedical research, when the promise of success is not obvious or guaranteed, can often be the engine that ensures innovative research moves forward, paving the way for important

discoveries and new and better therapies," said Laurie H. Glimcher, M.D., president and CEO of Dana-Farber Cancer Institute. "I am hopeful that this investment by Deerfield at Dana-Farber now will eventually help improve the lives of people with cancer everywhere."

Riverway Discoveries' goal is to push the most promising cancer candidates through preclinical development to advance the pipeline more swiftly, getting new treatments into the hands of patients as fast as possible to save more lives.

Just last month, Deerfield dropped $50 million to launch cancer startup Nuvalent. The Series A financing will help fuel Nuvalent's research and development efforts for a portfolio of innovative small molecule kinase inhibitors for programs in non-small cell lung cancer (NSCLC).

Eli Lilly's Antibody Combo Wins FDA Approval for Mild to Moderate COVID-19

FEBRUARY 10, 2021

The U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) to a combination of Eli Lilly and AbCellera's monoclonal antibody bamlanivimab and a second Eli Lilly antibody called etesevimab for mild to moderate COVID-19.

This combination therapy has been authorized for the treatment of mild to moderate COVID-19 in patients aged 12 and older who are at high risk for progressing to severe COVID-19 and/or hospitalization. Bamlanivimab and etesevimab should be administered together via a single intravenous infusion as soon as possible after a positive COVID-19 test and within 10 days of symptom onset, Eli Lilly said in its announcement.

The FDA previously granted EUA to bamlanivimab in November for a similar indication. New protocols enable front-line clinicians to administer bamlanivimab alone and bamlanivimab and etesevimab together in as few as 16 minutes and 21 minutes, respectively. Previously, the infusion took about an hour. Bamlanivimab and etesevimab are not authorized for patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19.

The EUA is based on Phase III data from the BLAZE-1 trial that showed the combination generated a reduction in hospitalizations of 70% of COVID patients. None of the patients who received the treatment died. The outcomes seen with the combination of bamlanivimab and etesevimab are consistent with the reduction in risk of hospitalization or ER visits seen with bamlanivimab alone, Eli Lilly said.

Both bamlanivimab and etesevimab are neutralizing recombinant human IgG1 monoclonal antibodies, and both target the SARS-COV-2 spike protein receptor binding domain to prevent entry into human cells. Bamlanivimab was first discovered by AbCellera from the blood of one of the first recovered COVID-19 patients in the United States. Lilly licensed etesevimab from Junshi Biosciences.

Gilead and Gritstone Ink $785 Million+ Deal to Develop HIV Cure

FEBRUARY 01, 2021

Gilead Sciences has inked a collaboration, option and license deal with Gritstone Oncology to create a vac-

cine-based immunotherapy as a cure for HIV.

The partnership will leverage Gritstone's proprietary prime-boost vaccine platform. This is made up of self-amplifying mRNA (SAM) and adenoviral vectors using antigens developed by Gilead.

Under the terms of the deal, Gilead is paying Gritstone $30 million in cash up front and a $30 million equity investment. Gilead will handle a Phase I trial for the HIV-specific vaccine and will hold an exclusive option for an exclusive license to develop and commercialize it beyond Phase I. Gritstone will be up for an additional $725 million in regulatory and commercial milestones, as well as mid-single-digit to low double-digit tiered royalties on net sales.

Brainard added, "Gritstone's vaccine technology has the potential to educate the immune system to specifically recognize and destroy HIV-infected cells by leveraging SAM and adenoviral vectors. This, along with our other partnerships and internal programs, reflects Gilead's commitment to continuing innovation to discover a cure for HIV and bring about an end to the HIV epidemic."

"The resulting strong, durable and broad anti-SIV CD8+ T cell responses and T cell data captured the attention of Gilead's virology team. We jointly performed further experiments that generated additional compelling data, which was also complemented by our exciting clinical data with neoantigens in cancer patients," said Karin Jooss, Gritstone's executive vice president of Research and chief scientific officer. "We are delighted to now advance our partnership and product candidates for the treatment of patients with HIV infection."

On January 20, Gritstone entered into licensing deal with Genevant Sciences to Genevant's lipid nanoparticle (LNP) technology to develop SAM vaccines against SARS-CoV-2, the virus that causes COVID-19. Genevant's LNP platform is already clinically validated and part of Gritstone's SAM neoantigen-based cancer immunotherapy that is currently in Phase II studies.

GSK and CureVac Take Aim at COVID-19 Variants with Second-Generation mRNA Vaccine

FEBRUARY 03, 2021

GlaxoSmithKline will partner with Germany's CureVac to manufacture 100 million doses of that company's mRNA COVID-19 vaccine, CVnCoV, and will collaborate with the company to develop a next-generation multi-valent COVID-19 vaccine aimed at emerging variants of the novel coronavirus.

The collaboration is valued at €150 million (approximately $180 million). The two companies already have a history of working together.

In July, the two companies partnered to develop up to five messenger RNA (mRNA)-based vaccines and monoclonal antibodies (mAbs) targeting infectious disease pathogens. The terms of that deal included GSK acquiring a 10% stake in the German company.

The latest collaboration between the two companies noted that GSK and CureVac will contribute resources and expertise to research, develop and manufacture a number of novel mRNA vaccine candidates, including multi-valent and monovalent approaches.

This collaboration will build on CureVac's first generation COVID-19 vaccine candidate CVnCoV, which is currently in Phase IIb/III clinical trial and on CureVac's ability to optimize mRNA for a strong immune response.

Under the terms of the new collaboration agreement, GSK will be the marketing authorization holder for the next-generation vaccine, except in Switzerland, and will have exclusive rights to develop, manufacture, and commercialize the next generation COVID-19 vaccine in all countries with the exception of Germany, Austria and Switzerland.

Last month, CureVac partnered with Bayer on the development of its first-generation mRNA vaccine. Under the terms of the agreement, Bayer will support the development, supply and key territory operations of CVnCoV. Bayer will contribute its "expertise and established infrastructure in areas such as clinical operations, regulatory affairs, pharmacovigilance, medical information, supply chain performance as well as support in selected countries," the companies said.

Lilly CFO Resigns Due to "Inappropriate Communication" with Multiple Employees

FEBRUARY 09, 2021

Anat Ashkenazi was tapped to take over as chief financial officer of Eli Lilly following the abrupt resignation of Josh Smiley, who departed the company following allegations of an inappropriate relationship with an employee.

This morning, Eli Lilly said it was made aware of the allegations of that inappropriate relationship between Smiley and the employee and immediately conducted an independent investigation.

The investigation found that Smiley, who became CFO in 2016, engaged in inappropriate personal communications with multiple employees, however, they were deemed to be consensual. Despite that consent, Eli Lilly said its leadership team determined Smiley exhibited poor judgment.

"Lilly holds all employees accountable to its core values and strongly believes its executive officers carry an even higher burden in ensuring those values are upheld. Mr. Smiley did not meet that standard," the company said in its announcement.
David Ricks, chairman and chief executive officer of Eli Lilly, said the company's core values are "integrity,

excellence and respect for people." Those values are to be adhered to by all employees and executives are expected to display exemplary conduct at all times, he said. Ricks added the company's appreciation for Smiley's "many contributions to Lilly" and wished him well in his future endeavors.

Smiley's conduct was not related to financial controls, financial statements or any other business matters or judgments, the company said. As such, he will be allowed to assist in the transition of his duties to Ashkenazi, who most recently served in the role of senior vice president, controller and chief financial officer of Lilly Research Laboratories.

Lonza to Sell Specialty Ingredients Division for $4.7 Billion

FEBRUARY 09, 2021

Basel-based Lonza AG is moving to sell its Lonza Specialty Ingredients (LSI) division to private equity firms Bain Capital and Cinven for CHF 4.2 billion ($4.7 billion), completing a planned pivot to focus on its Lonza Pharma, Biotech & Nutrition business.

In its year-end financials last month, Lonza reported sales of CHF 4.5 billion ($5 billion) and sales growth of 12.0%, largely on the back of its health care group.

Lonza has been in the process of separating LSI into a standalone unit since 2019. Sales had slumped relative to its pharmaceutical business, and the company brought in Roche and Novartis veteran Pierre-Alain Ruffieux as CEO in November to steer the business in this new direction.
Lonza's life sciences business includes a partnership with Moderna to manufacture its COVID-19 vaccine, in facilities at Portsmouth, New Hampshire, and in Switzerland.

LSI, which employs about 2,800 people at its 17 manufacturing and 11 research and development sites globally, specializes in microbial control solutions like disinfectants, preservatives and sanitizers. It also produces industrial chemicals and, at its Switzerland facility, more specialized chemicals, for the electronics, aerospace, food and agrochemical industries.

Last year, LSI's head Sven Abend, then Lonza's chief operating officer, left to become CEO of collagen protein supplier Gelita.

FDA Approves ViiV's Monthly Shot for HIV

JANUARY 22, 2021

The U.S. Food and Drug Administration (FDA) gave a greenlight for ViiV Healthcare's Cabenuva. The drug, a combination of cabotegravir and rilpivirine, is a complete therapy for HIV-1 infection in adults who are virologically suppressed, which is defined as having HIV-1 RNA of less than 50 copies of the virus per milliliter on a stable treatment regimen, no history of treatment failure and no known or suspected resis-

tance to either of the drugs in the combination. The shot is given as two intramuscular injections in the buttocks once a month at a specialist clinic.

ViiV Healthcare focuses on HIV and is majority-owned by GlaxoSmithKline (GSK), with Pfizer and Shionogi Limited as shareholders. Cabotegravir is a ViiV product marketed as Cabenuva, and rilpivirine is a Janssen product with a brand name Edurant. Janssen is a Johnson & Johnson company.

The approval was built on the Phase III ATLAS and FLAIR trials. These involved more than 1,100 patients from 16 countries. Before beginning treatment with Cabenuva, patients took oral doses of both cabotegravir and rilpivirine for about a month to determine if the patients could tolerate it.

In the trials, Cabenuva was as effective as a daily oral three-drug regimen. The once-a-month regimen was preferred by nine out of 10 patients over the daily oral therapy.

In addition to the ATLAS and FLAIR trials, ViiV sponsored the CUSTOMIZE clinical trial. This was the first-ever, pre-approval implementation science study developed to evaluate ways to integrate Cabenuva into U.S. clinical practices.

Cabotegravir is an integrated strand transfer inhibitor (INSTI). Rilpivirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI).

MediBuddy wraps up $40M Series B Round

FEBRUARY 02, 2021

Bengaluru based startup MediBuddy has announced the closure of its $40 Million Series B Round. This follows the recent infusion of $20 million led by India Life Sciences Fund III, LLC, with participation from

other investors. The digital healthcare platform had earlier announced an initial funding of $20 million (Rs 150 crore) in June 2020 under this round.

Satish Kannan, Co-Founder & CEO, MediBuddy, added that the potential of the MediBuddy platform has generated significant investor interest in the Series B round despite the uncertainty prevalent worldwide, helping it secure the highest funding in the digital healthcare space since the start of the pandemic. He also said that the Series B round attracted new investments from India Life Sciences Fund III, LLC, TEAMFund LP, JAFCO Asia Fund, FinSight Ventures, ALES Global Japan and Beyond Next Ventures. Existing investors including Bessemer Venture Partners, Milliways Ventures and Rebright Partners also participated in this round.

Vikul Goyal, Venture Partner, FinSight Ventures, said, "MediBuddy is by far the leader in the digital health-

care space in terms of scale, size & customers served; and we are excited to partner with MediBuddy in this growth journey to make high-quality healthcare accessible to a billion Indians." Devarajan TP, Managing Director, representative of India Life Sciences Fund III, LLC, on the Board, said, "The Fund's representatives look forward to working with MediBuddy and supporting it in its endeavour to emerge as India's preferred digital healthcare platform."

Yousuf Mazhar, Managing Partner, TEAMFund, said, "TEAMFund is very excited to partner with the team at MediBuddy, and is looking forward to helping build out their chronic disease management capabilities for remote patients."

The digital healthcare platform will utilise the funding in further strengthening its doctor and hospital base, patient reach, product, technology and brand to move a step closer to its mission of providing high-quality healthcare to a billion people.

Merck and Bayer Win FDA Approval for Heart Failure Drug

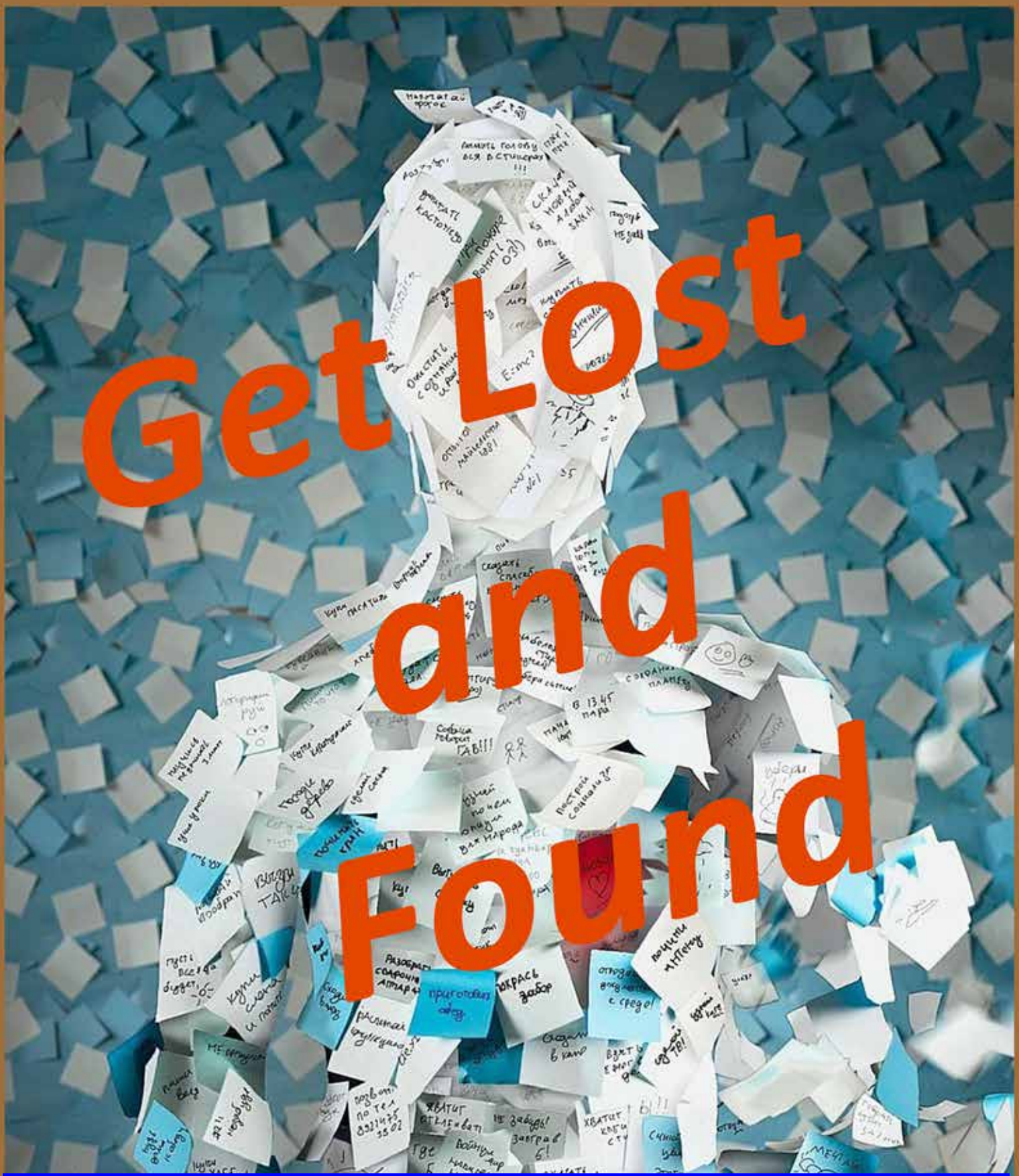
JANUARY 20, 2021

The U.S. Food and Drug Administration (FDA) approved Merck and Bayer's heart failure drug vericiguat, an orally administered soluble guanylate cyclase (sGC) stimulator.

Vericiguat will be marketed under the brand name Verquvo and is the first treatment for chronic heart failure approved specifically for patients following a hospitalization for heart failure or need for outpatient IV diuretics. Specifically, it was approved to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous (IV) diuretics in adults with symptomatic chronic heart failure and ejection fraction less than 45%.

Verquvo, which was jointly developed with Bayer, was approved under priority review based on results from the Phase III VICTORIA study. The VICTORIA study met the primary endpoint by demonstrating a statistically significant reduction of the first occurrence of a composite of cardiovascular death or heart failure hospitalization. The trial was assessing the efficacy of the medication in those patients' chronic heart patients with reduced ejection fraction (HFrEF). Vericiguat was being tested in combination with available heart failure therapies against placebo. Over the course of the study, there was a 4.2% reduction in annualized absolute risk with Verquvo compared with placebo. Therefore, 24 patients would need to be treated over an average of one year to prevent one primary endpoint event, the companies said in a joint statement.

Roy Baynes, head of global clinical development and chief medical officer at Merck Research Laboratories, said clinical studies have shown Verquvo is able to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics.



Biotech Express magazine put forward all the news and articles related to biotechnology in front of its diverse audience. Since Biotechnology is amalgamation of different branches of science, we also try to include updates from several disciplines. This magazine would like to take you near the greatest people from field through interviews which will surely help to carve out the decision process by knowing nitty-gritty of the field.

Merck Shutters COVID-19 Vaccine Programs, Shifts Focus to Therapeutics

JANUARY 25, 2021

Merck announced that it is going to stop developing its two COVID-19 vaccine candidates, dubbed V590 and V591, after poor responses in Phase I trials. They are shifting their attention to advancing two therapeutic drugs for COVID-19, MK-4482 and MK-7110.

Merck came late to the vaccine race when it acquired Austria-based Themis in May 2020. The same month, it partnered with Florida-based Ridgeback Therapeutics to develop MK-4882, which is an orally-available antiviral candidate. And in November, it acquired Maryland-based OncoImmune and its COVID-19 candidate CD24Fc (MK-7110) for $425 million in upfront cash.

In the Phase I trials, V590 and V591 were generally well tolerated, but the company reports that immune responses were inferior to what was observed in people who recovered naturally from COVID-19 infections.

Merck has a history of successful vaccine development, so it was a bit surprising when they came so late to the COVID-19 vaccine arena. They chose a traditional approach of utilizing weakened viruses. The V590 leveraged technology from the company's Ebola vaccine, and the V591 tech is based on a measles vaccine utilized in Europe. The company only finished recruiting volunteers for the Phase I study close to the end of 2020, while Pfizer-BioNTech and Moderna were at that time already reporting Phase III data and submitting packages to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA). Both companies' COVID-19 vaccines are being dosed throughout the U.S. and Europe.

Molecular Templates forges Cancer Deal with BMS Worth up to $1.3 Billion

FEBRUARY 12, 2021

Texas-based Molecular Templates (MTEM) and Bristol Myers Squibb forged a strategic research collaboration worth a potential $1.3 billion to discover and develop multiple oncology therapies using a next-generation engineered toxin body (ETB) platform.

The ETB technology platform was developed by Molecular Templates. ETBs represent a new class of targeted therapeutics that act through differentiated mechanisms of actions including the ability to force receptor internalization, deliver therapeutic payloads, and directly kill targeted cells through the enzymatic

inactivation of ribosomes, the company said.

Both BMS and Molecular Templates hope they will be able to discover new molecules with the ETB platform. According to MTEM, ETBs use a genetically engineered form of Shiga-like Toxin A subunit, or SLTA, a ribosome inactivating bacterial protein, that can be targeted to specifically destroy cancer cells.

Under terms of the agreement, Molecular Template will undertake research responsibilities for the discovery of next-generation ETBs for multiple targets. BMS has already selected a target, but that was not disclosed by the companies in the announcement. If the ETBs are promising, BMS will have the option to develop and commercialize the assets.

BMS will make an up-front payment of $70 million to MTEM. As the project moves forward, and other targets are selected, Molecular Templates could receive up to $1.3 billion in milestone payments. The company would also receive tiered royalty payments on future sales.

GSK Divests Antibiotics Business to Sandoz for $500 Million

FEBRUARY 12, 2021

Sandoz, a division of Swiss-based Novartis, inked a deal to buy U.K.-based GlaxoSmithKline's cephalosporin antibiotics business.

Under the terms of the deal, Sandoz is paying GSK $350 million at closing and additional milestones up to $150 million. The agreement includes global rights to three brands, Zinnat, Zinacef and Fortum in more than 100 countries. Some of those rights are excluded in the U.S., Australia and Germany, which were previously divested by GSK. Also, GSK is holding onto the rights to some brands in India, Pakistan, Egypt, Japan and China.

"This important transaction will further position Sandoz as a global leader in antibiotics—truly essential medicines that are the backbone of modern healthcare systems," said Richard Saynor, chief executive officer of Sandoz. "Cephalosporins are the largest antibiotic segment by global sales and acquiring this leading business, including the established global Zinnat brand, will complement our #1 position in generic penicillins, the other key segment. It will also set us up for additional synergies driven by an increased promotional footprint that will support growth of both the acquired brands and the current existing Sandoz portfolio."

On the part of GSK, it is dividing itself into two companies, one focused on over-the-counter (OTC) products and the other on prescription drugs and vaccines. GSK indicates that the deal aligns with its strategy of prioritizing and simplifying its portfolio while investing in its research-and-development pipeline and new product launches. After a four-year manufacturing and supply agreement (MSA), manufacturing of cephalosporin will transfer from GSK locations to Sandoz. GSK plans to close its cephalosporins manufacturing operations once that transfer is complete, which is expected in 2025. GSK indicated it is "providing support

to potentially affected employees and is committed to supporting the local communities affected."

PacBio Secures $900 Million Investment to Support Gene Sequencing

FEBRUARY 10, 2021

Shares of Pacific Biosciences (PacBio) soared more than 21% in premarket trading after it was announced SB Management, a subsidiary of SoftBank Group Corp., will make an investment of $900 million into the company to support its gene sequencing research.

California-based PacBio's Chief Executive Officer Christian Henry said the SoftBank investment validates the company's position in the long-read DNA sequencing market and will also enables the acceleration of its growth strategies. Henry said the financing will enable PacBio to expand its product portfolio and advance its commercial expansion.

SoftBank will purchase $900 million in Convertible Senior Notes at a price of $43.50 per share, which represents a 10% premium to the closing price on Feb. 9. In premarket trading, the stock has jumped to $47.90 per share.

Regarding the massive infusion of cash into PacBio, Akshay Naheta, CEO of SB Management, said Softbank believes the company's sequencing technology will be the "de facto standard tool for population genomics fundamentally altering the practice of healthcare." Naheta touted the leadership at PacBio and said Softbank is excited about partnering with the company as it aims to "build the most advanced genome sequencing platform in the world."

PacBio's long-read sequencing is based on the SMRT (Single Molecule, Real-Time) technology. The company said its technology offers the most comprehensive view of genomes, transcriptomes and epigenomes—including the full spectrum of genetic variation—by providing the longest average read lengths, highest consensus accuracy, and most uniform coverage of any sequencing technology currently available.

For PacBio, the SoftBank investment comes about a year after its merger with Illumina was called off. The $1.2 billion merger was initially announced in November of 2018, but was terminated in early 2020 due to a lengthy regulatory approval process and "continued uncertainty" of the outcome of the merger. As a result of the mutual decision to terminate the agreement, sequencing giant Illumina paid Pacific Biosciences a $98 million termination fee.

Roche Washes Hands of Mid and Late-Stage Trial Failures

FEBRUARY 04, 2021

The Swiss pharma giant announced in its earnings report that it was terminating studies of several mid- and late-stage assets, including two late-stage breast

cancer programs.

In its fourth-quarter presentation, Roche noted several programs that have been terminated after earlier clinical trial failures in 2020. Roche included a checklist for ongoing programs and the ones that have been terminated included a large, red X. One of the studies terminated is the Phase III IMagyn050 trial assessing a combination of two previously approved cancer drugs. The study was seeking to determine if adding Tecentriq (atezolizumab) to a combination of Avastin (bevacizumab), paclitaxel and carboplatin would make a difference in the treatment of women with newly diagnosed advanced-stage ovarian cancer. It did not. The addition of Tecentriq did not improve progression-free survival to the first-line combination therapy.

Another program terminated is the Phase III IPATunity130 study. That trial was assessing ipatasertib, an Akt inhibitor, and chemotherapy for the treatment of patients with PIK3CA/AKT1/PTEN-altered hormone receptor-positive, HER2-negative advanced breast cancer. The trial failed to meet its endpoints of both progression-free survival and objective response rate. AKT1/2/3, which ipatasertib inhibits, is the central node of the PI3K/AKT pathway, which plays a critical role in HR-positive, HER2-negative breast cancer. Although ipatasertib missed the mark in the breast cancer study, Roche is still investigating its use in other cancers. Last year, the asset hit the mark in the Phase III IPATential150 study in patients with metastatic castration-resistant prostate cancer whose tumors had PTEN loss. Ipatasertib in combination with abiraterone and prednisone/prednisolone provided a statistically significant reduction in the risk of disease worsening or death, the company said at the time.

The other Phase III program culled by Roche is a combination of idasanutlin, an MDM2 antagonist, and chemotherapy for the treatment of acute myeloid leukemia. The combination failed to reach endpoints of improving survival in the late-stage MIRROS program. Roche had hoped to determine if the addition of idasanutlin to chemotherapy would prove superior to chemotherapy alone. The addition of the MDM2 antagonist did not prolong life in those patients. Although idasanutlin failed in the MIRROS trial, Roche and Genentech are investigating it along with Venclexta in patients with relapsed or refractory AML who are not eligible for chemotherapy.

It wasn't just late-stage programs that saw the proverbial axe. Roche also terminated two mid-stage programs in ulcerative colitis and autism spectrum disorder. Roche subsidiary Genentech reported etrolizumab demonstrated a mixed bag in a Phase III ulcerative colitis test. While the drug hit its endpoint of inducing remission versus placebo, it failed to meet its primary endpoint versus placebo as maintenance therapy in people with ulcerative colitis.

The autism study that Roche terminated involved an asset that received Breakthrough Therapy designation in 2018. Last year, Roche announced it was terminating the trial assessing balovaptan, a vasopressin 1a (V1a) receptor antagonist. Roche stopped the Phase II study of balovaptan early last year following a futility assessment.

Servier and MiNA Partner to Create Entirely New Class of Drugs

January 21, 2021

France-based Servier and U.K.-based MiNA Therapeutics are partnering on small activating RNA (saRNA) therapies to treat neurological diseases. saRNA is an entirely new class of drugs. They are small oligonucleotides, similar to siRNAs. This technology is MiNA's focus, based on inventions from the company's founder Pål Saetrom, which were assigned to MiNA by the Norwegian University of Science and Technology. The company has also in-licensed fundamental patents from UT Southwestern Medical Center that covers RNA activation therapeutics.

MiNA will leverage its saRNA platform to identify

possible treatments to restore normal cell function in neurological diseases. Servier will handle preclinical and clinical development of potential candidates. Servier also will have the option for commercialization of any products coming out of the partnership.

Servier is paying MiNA an undisclosed payment up front and an exclusivity fee on specific neurological targets. MiNA is also up for various milestones and royalties. MiNA is eligible for up to 220 million euros ($268 million, U.S.) in upfront, development and commercial milestone payments for the first target. No specific neurological indications were disclosed.

"MiNA's innovative approach to activate gene expression through small activating RNAs is an exciting opportunity to unlock potential for the treatment of genetically defined neurodegenerative diseases, for which there are currently limited treatment options," said Ross Jeggo, Head of the Servier Neurology and Immuno-inflammation Therapeutic Area. "We are delighted to welcome the MiNA team and to combine their unique approach to restoring cellular function with Servier's focus on treating neurological diseases."

MiNA's pipeline currently consists of five compounds, three in the discovery stage for undisclosed metabolic, immuno-oncology and genetic targets. The other two programs are for the same drug, MTL-CEBPA, which are in Phase I/II trials, one with Bayer and Onyx Pharmaceuticals Nexavar (sorafenib) for hepatocellular carcinoma (HCC) and the other with Merck's checkpoint inhibitor Keytruda (pembrolizumab) for advanced solid tumors.

Thermo Fisher Buys Mesa Biotech for a Total Deal of $550 Million

January 19, 2021

Thermo Fisher Scientific, based in Waltham, Massachusetts, is acquiring Mesa Biotech for about $450 million in cash. There is also an additional $100 million in cash after certain milestones are hit.

Mesa Biotech, based in San Diego, California, is a privately held molecular diagnostic company. It has developed and markets a PCR-based rapid point-of-care testing platform for infectious diseases, including SARS-CoV-2 (COVID-19), flu A and B, respiratory syncytial virus (RSV) and Strep A. Mesa has about 500 employees and in 2020 reported revenue of about $45 million.

Its Accula Flu A/FluB, RSV and Strep A tests were granted 510(k) clearance and Clinical Laboratory Improvements Amendments (CLIA) waivers from the U.S. Food and Drug Administration (FDA). The Accula System also received Emergency Use Authorization from the FDA for COVID-19 in vitro testing and is currently available in patient care settings. It offers results in about 30 minutes.

The Accula Strep A test is the third molecular POC diagnostic on the Accula platform to receive FDA clearance and CLIA waiver. The earlier ones were Flu A/Flu B and RSV.

Last week, Thermo Fisher completed its acquisition of Henogen SA, Groupe Novasep SAS's viral vector manufacturing business in Belgium. That deal was for €725 million in cash. That was a string of deals over the last couple years to bolster its viral vector manufacturing for use in gene and cell therapies. Other acquisitions in that space include Brammer Bio for $1.7 billion in March 2019, and the investment of $50 million in a manufacturing site the same year in St. Louis County. In August 2017, the company acquired contract development and manufacturing organization (CDMO) Patheon for $7.2 billion.

Bio Controversies

False phone numbers, fake names: How Bihar Covid testing data got infected and led to termination of officials

FEBRUARY 10, 2021

Bihar health secy says huge discrepancies found in Covid-19 test data

Bihar's principal health secretary Pratyay Amrit on Saturday stated that "serious discrepancies" in Covid-19 test data has been found in Jamui's Barhat and Sikandra. He also said action has been initiated against concerned officials.

Over three days last month, three Primary Health Centres (PHC) in Bihar's Jamui district tested 588 residents for Covid — all were negative. The name, age and cell number of each person tested was put down in a chart and sent to Patna where it was aggregated with data from other districts to plot the state's downward Covid curve. Staring out from these charts, however, are a string of glaring irregularities, an investigation by The Indian Express has revealed.

The Indian Express visited six PHCs in Jamui, Sheikhpura and Patna, and accessed their testing records for January 16, 18 and 25. In Jamui, it tracked down each of the 588 entries at three PHCs for those days, and spoke to several staffers to find that basic data protocol was bypassed in a scramble to meet the daily target — from fudged mobile numbers to fake names and dodgy entries. And, in some cases, to allegedly siphon off profits from unused testing kits.

Some of the key findings of the investigation from official records of tests carried out on those three days:

Of 230 entries for Barhat in Jamui, only 12 entries were confirmed tested. At the Sikandara PHC in the district, only 43 of 208 entries were confirmed tested.

And in Jamui Sadar, only 65 of the 150 entries could be verified against data recorded.

In Barhat, the cell number used against 14 entries and another for 11 entries tested on January 16 were both invalid. So was the case with another number used for 13 entries for testing on January 25. In Sikandara, cell numbers listed against 16 entries were found invalid.

There is just one mobile number mentioned against as many as 26 who got the RT-PCR tests in Barhat. This number belongs to Baiju Rajak, a daily wager from Shambhuganj in Banka, about 100 km away. "I have no connection to any of these people, no one in my family has got tested for Covid," Rajak said.

The 26 people with this number include: 11 men, six women and nine children. The names and numbers are being withheld to protect identities.

Records in Sheikhpura district's Barbigha of January 25 show that Sonali Kumari and Ajeet Kumar tested negative in a Covid test. But the phone number used for them belonged to Vijay Kumar, a sweets shop owner in UP's Pratapgarh. "I do not know these people and I don't have any Bihar connection. I have not taken any Covid test," Kumar told The Indian Express.

Bihar was among the states hardest-hit by the pandemic with the return of over 20 lakh migrant workers as infections peaked in the middle of last year. The state has so far recorded 2,61,447 positive cases with 754 currently active, and 1,518 deaths linked to Covid.

While Patna tops the state's Covid chart with over 52,000 cases so far, records from Jamui and Sheikhpura show how in several cases, the mobile numbers provided for those tested were owned by unrelated people from other districts or states. In some cases, multiple unrelated persons were listed under one number. In a few cases, numbers used were those of the PHC staffers themselves.

Fresenius Kabi, India hid "Dirty Laundry" from FDA, Pleads Guilty to Criminal Charges

FEBRUARY 11, 2021

Germany-based Fresenius Kabi (FKOL) is the kid who was told to clean up their room before mom came home and instead hid the dirty laundry under their bed. Except in this case the dirty laundry was manufacturing records and the mom coming up for inspection was the U.S. Food and Drug Administration (FDA).

Right before the FDA came from an inspection of the company's manufacturing plant in Kalyani, West Bengal in 2013, court documents say company "management directed employees to remove certain records from the premises and delete other records from computers that would have revealed FKOL was man-

ufacturing drug ingredients in contravention of FDA requirements."

The cancer drugmaker pled guilty of violating the Federal Food, Drug and Cosmetic Act by failing to provide certain records to investigators in federal court. Instead of a time out, FKOL will pay $50 million in fines and forfeitures, according to the Justice Department.

"By hiding and deleting manufacturing records, FKOL sought to obstruct the FDA's regulatory authority and prevent the FDA from doing its job of ensuring the purity and potency of drugs intended for U.S. consumers," said Acting Assistant Attorney General Brian Boynton of the Justice Department's Civil Division. "FKOL's conduct put vulnerable patients at risk. The Department of Justice will continue to work with the FDA to prosecute drug manufacturers who obstruct these inspections."

One of the manufacturing plant's undercover practices was blending failed ingredient batches with batches that had passed testing so the final result would meet purity specifications. Employees also used test and demo chromatogram data files to fudge testing results to show the batch was in conformity with regulations.

In addition to pleading guilty to these federal misdemeanor charges, FKOL also agreed to implement some new housekeeping protocols to keep things on the up and up including a compliance and ethics program designed to prevent, detect, and correct violations of US law relating to FKOL's manufacturing processes.

A quick search pulls up a slew of issues over the years for the pharma company. In 2015, the company paid a fine close to $700,000 after a diabetic patient in the U.K. died after being injected with faulty syringes containing no insulin.

Last April, 13 lots of the Ketoralac Tromethamine injection were recalled due to particulate matter found in the sample vials. Using a product with particulate matter can obstruct and irritate blood vessels, cause swelling, inflamed and infected tissue, blood clots that can scar lung tissue and life-threatening allergic reactions.

Three years before that the company recalled a lot an injectable general anesthesia drug after discovering the syringes were mislabeled and actually contained a completely different drug intended for chemo and post-op patients suffering from nausea and vomiting.

This case also isn't the first negative run-in Fresenius Kabi's West Bengal plant has had with the FDA. In 2017 the company was issued a warning letter regarding observations that staffers were gaming the quality control system. If a drug quality test showed a problem, staff would stop the test, inventing some error that could have caused the impurity in the batch.

The letter also referred to a previous warning letter from the 2013 visit that said, "these repeated failures demonstrate that your facility's oversight and control over the manufacture of drugs is inadequate."

Hundreds of 'predatory' journals indexed on leading scholarly database

February 08, 2021

"There are potentially serious consequences of predatory articles being indexed in scientific databases," says Anna Severin, a sociologist who studies peer review at the University of Bern and has written about predatory journals infiltrating citation databases2. "Researchers might base their further research on poor-quality or even fabricated findings and cite these in their own publications, thereby further distributing untrustworthy science," says Severin, who wasn't involved in the latest study.

Predatory journals are those that tend to publish low-quality science and deviate from best editorial

practices. They might use false or misleading information, or aggressive solicitation practices, and collect fees for publishing work that undergoes little editorial scrutiny. Researchers have previously found that some such journals are indexed in popular scholarly databases such as the biomedical site PubMed3, but the extent of the problem is difficult to quantify.

To conduct the latest analysis, published in Scientometrics on 7 February1, Vít Macháček and Martin Srholec, economists based at an economic institute run by Charles University and the Czech Academy of Sciences in Prague, compared the titles indexed in Scopus with a list of potentially predatory journals that was maintained by former librarian Jeffrey Beall until 2017. They found 324 of these questionable journals on the database; collectively these titles published some 164,000 papers between 2015 and 2017. That's around 2.8% of the total number of papers indexed in the database during that period.

Scopus, which is run by the Dutch publisher Elsevier, says that it has stopped indexing new content for 65% of all journals that are flagged to it for re-evaluation because of concerns about publishing practices. That means that papers from these titles are no longer added to the database — however, old content remains indexed, a spokesperson says. "Scopus is vigilant in identifying and discontinuing journals that are, or have become, predatory," they told Nature. Scopus's content-selection board evaluates and regularly reviews the inclusion of journals in the database, checking whether they meet certain metrics thresholds.

The inclusion of predatory journals in databases is problematic because it means that they can inflate author metrics, say physiologists Andrea Manca and Franca Deriu at the University of Sassari in Italy, who worked on the study identifying predatory journals in PubMed. This can make a difference in countries where career advancement strictly depends on these metrics.

In 2017, in an effort to address the problem of predatory journals, PubMed issued guidelines on the titles authors should publish in. But keeping track of these titles is difficult, say Manca and Deriu. "Predatory journals are continuously changing names and publishers, and keep growing in number as we speak."

Millions earmarked for public health emergencies were used to pay for unrelated projects, US inspector general says

JANUARY. 27, 2021

Federal officials repeatedly raided a fund earmarked for biomedical research in the years leading up to the covid-19 pandemic, spending millions of dollars on unrelated salaries, administrative expenses and even the cost of removing office furniture, according to the

findings of an investigation into a whistleblower complaint shared with The Washington Post.

The investigation, conducted by the inspector general of the Department of Health and Human Services and overseen by the Office of Special Counsel, centered on hundreds of millions of dollars intended for the development of vaccines, drugs and therapies by the Biomedical Advanced Research and Development Authority or BARDA, an arm of the federal health department.

The unidentified whistleblower alleged that officials in the office of the assistant secretary for preparedness and response at HHS, which oversaw the biomedical agency, wrongly dipped into the money set aside by Congress for development of lifesaving medicines, beginning in fiscal 2010 and continuing through at least fiscal 2019, spanning both the Obama and Trump administrations.

The inspector general substantiated some of the whistleblower's claims, finding that staff referred to the agency as the "bank of BARDA" and told investigators that research and development funds were regularly tapped for unrelated projects, sometimes at "exorbitant" rates.

"I am deeply concerned about [the] apparent misuse of millions of dollars in funding meant for public health emergencies like the one our country is currently facing with the covid-19 pandemic," Special Counsel Henry Kerner wrote in a letter to President Biden on Wednesday. "Equally concerning is how widespread and well-known this practice appeared to be for nearly a decade."

The inspector general concluded that the agency violated the Purpose Statute, a cornerstone of federal law designed to ensure that funds appropriated by Congress are used for their intended purpose.

COVID-19 PCR testing paper, "the criteria for a retraction of the article have not been fulfilled

Two months after announcing it would review an early 2020 paper on a way to detect the virus that causes COVID-19, a journal says that "the criteria for a retraction of the article have not been fulfilled."

The review of the paper, "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR, by the journal, Eurosurveillance, was prompted by critiques including a petition by some 20 people around the world for what they called "scientific and methodological blemishes." The senior author of the Eurosurveillance paper, Christian Drosten, of the Charité University Hospital in Berlin, has been a leader in the fight against the pandemic, but has also predictably drawn criticism from those who oppose lockdowns.

On December 3, the journal issued a statement saying they were reviewing the allegations, which, as editors note in their statement dated yesterday:

Allegations concerned the scientific quality of the article, the peer review process and a conflict of interest for two of the authors, who are also editorial board members of Eurosurveillance.

Those two authors were excluded from the review, according to the journal.

The editorial board of the journal found that "there was no conflict of interest by the associate editors who co-authored the manuscript" and "further decided to involve external subject experts to assess the allegations related to the scientific content of the article."

The editors note that

articles submitted by members of the board are not given any priority over other manuscripts. When editorial board members are authors of a submitted manuscript, they are not involved in any stage of the peer review or the editorial decision-making, nor do they have access to confidential information related to the decision-making process.

The statement continues:

The speed of the publishing process has led to allegations via social media and email that the evaluation and review process were flawed. The Eurosurveillance editorial team has long-standing experience in expedited publishing in instances when rapid dissemina-

tion of information could potentially lead to a prompt change in an ongoing public health situation or create awareness for topics of timely relevance. In such instances, the editorial team works in close coordination with reviewers and authors. Since 2015, about 30% of rapid communications have been published less than 2 weeks following submission, including peer review. This has also been the case for a maximum of two regular articles per year. Eurosurveillance's in-house editorial team performs most editorial and all publishing tasks, without involvement of external parties such as typesetters. This allows for great flexibility, particularly in times of emerging or evolving public health emergencies [4–6], when case numbers or other relevant information/data can be updated even hours before publication.

The editors conclude:

The detailed allegations with respect to scientific flaws in the Corman et al. article were reviewed by a group of five laboratory experts. These comments were made available to the Eurosurveillance associate editors, except for those who were co-authors of the paper.

The consulted experts confirmed that the Corman et al. article was scientifically adequate for its purpose and for the limited data and material available at this early stage in the COVID-19 pandemic. Any laboratory deciding to use the primers and protocol suggested in this article would ascertain the assay for its fitness for purpose and compliance with local quality and accreditation requirements; this is what has happened worldwide since the publication of the article. With more data and evolving knowledge, laboratories have since further improved the initial method, as per usual practice.

In conclusion, after a thorough investigation in which we collected scientific advice from various sources, including several external reviewers, the editorial team—unanimously supported by its associate editors, except for those who were involved as co-authors—has decided that the criteria for a retraction of the article have not been fulfilled.

India: Lack of transparency on COVID vaccine goes against Centre's draft science policy

January 25, 2021

While scientists and researchers have been calling for transparency in COVID-19 vaccine-related research data, the Centre, ironically, released the draft version of the Science, Technology, and Innovation Policy (STIP) in December 2020 based on the ethos of "Open Science".

Open Science has emerged as a global movement amidst a growing crisis in science that has affected India as well, and includes issues such as fabrication and falsification of data, plagiarism, unethical authorship, failure to disclose funding sources and gender disparity in research institutions. An interesting example to understand the crisis is the "10,000 steps a day to remain healthy" goal, which most of us are aware of. How many, however, know that this goal is based on bad science and there is no evidence for the 10,000 steps figure?

Open Science draws attention to some core values such as transparency, accessibility, collaboration, and "constant and continuous transfer of knowledge between producers and users of knowledge." It's also an essential part of the draft STIP 2020, which states that an "all-encompassing Open Science Framework will be built to provide access to scientific data, information, knowledge, and resources to everyone" and "all data used in and generated from publicly funded research will be available to everyone under FAIR (findable, accessible, interoperable and reusable) terms".

However, the news on the "Emergency Use Authorisation" (EUA) to the two COVID-19 vaccine candidates, whose efficacy data is either currently unavailable or disputable in the Indian context, leads one to wonder if there is an inconsistency between policy and practice.

When data is not openly available, especially in cases of publicly-funded research and research which have wider public safety concerns, the vaccine for instance, not only is public trust in science and scientists damaged, the self-critical and self-correcting nature of science is severely hampered as well. The government's intention to prioritise research and innovation in the fight against the COVID-19 pandemic is laudable. A vaccine, however, cannot come at the cost of transparency, an indispensable element in the fight against the virus. While CDSCO guidelines clearly mention that "adequate data should be generated" to ensure safety and effectiveness of any vaccine whose development is expedited for unmet medical needs of the country, this data should also be made public.

Going ahead, data across the different stages of COVID-19 vaccine research (including but not limited to research methodology, research tools, negative results, efficacy data, and other limitations) should be made public on ICMR's open access repository, the central repository of the Department of Science and Technology or other open access repositories identified by the CSIR. This must be done on a priority basis to ensure that bad science does not compromise peoples' health and the trust in science remains intact.

Publisher retracting 68 articles suspected of being paper mill products

January 25, 2021

The Royal Society of Chemistry is retracting 68 articles, across three of its titles, after an investigation turned up evidence of what it suspects was the "systemic production of falsified research." The society said it is in the process of beefing up its safeguards against milled papers and plans to train its editors to have "extra vigilance in the face of emerging, sophisticated digital fraud."

That sounds much like what science sleuth Elisabeth Bik and others have found in hundreds of papers "that all appear to contain Western blots with the exact same background, often accompanied by hairball-like flow cytometry plots," and other signs of manipulation like templatized text and plagiarism. (Bik tells us she was not behind the 68 new retractions.)

According to a statement released Wednesday by the RSC:

We are retracting 68 articles that have been published in RSC Advances, with a small number of articles also to be retracted from RSC Medicinal Chemistry and Food and Function. These retractions are on the basis of what we believe to be the systemic production of falsified research, and we are one of a number of publishers to have been affected by such activity.

We take a zero tolerance approach to any alleged fraud in our journals and will be informing institutions and funders where evidence and investigation shows an individual has or may have submitted fraudulent research in their name.

This latest incident is the result of an organised and sophisticated operation, summed up as what is known as a "paper mill". We will be sharing insights and experience of this with colleagues across the publishing community, as part of a concerted, coordinated effort to stamp out falsified research.

Bio Policy

Biden Launches 10 Health-Focused Executive Orders on First Day in Office

January 21, 2021

Hours after being sworn in as the 46th President of the United States, Joe Biden signed 10 executive orders that are aimed at combating the ongoing COVID-19 crisis.

Among the orders signed by the newly sworn-in president, one order mandates the wearing of face masks on federal property, and also requires masks on public transportation. The Biden order also calls for travelers entering the country to have a negative COVID test before being allowed to enter.

Biden also directed government agencies to use wartime powers that require companies to make masks, swabs and other equipment to fight the pandemic. The act was previously used by the Trump administration to make ventilators used by hospitals for the most serious COVID-19 patients in intensive care units. The order also stresses the importance of increased testing, as well as an increase of funds to states and local governments to help with vaccines. "To control the COVID-19 pandemic and safely reopen schools and businesses, America must have wide-spread testing," the plan says, according to a CNBC report.

European Commission authorizes eight GMO crops for use as food and feed

January 26, 2021

The European Commission authorized five genetically modified crops (three maize and two soybeans) and renewed the authorization for three maize crops used for food and feed. All of these GMOs have gone

through a comprehensive and stringent authorization procedure, including a favorable scientific assessment by the European Food Safety Authority (EFSA). The authorization decisions do not cover cultivation.

Member States did not reach a qualified majority either in favor or against the Standing Committee and the subsequent Appeal Committee. The European Commission has therefore the legal duty to proceed with the authorizations.

The authorizations are valid for ten years, and any product produced from these GMOs will be subject to the EU's strict labeling and traceability rules.

The European Union (EU) has in place a comprehensive and strict legal regime on genetically modified organisms (GMOs), food and feed made from GMOs, and food/feed consisting or containing GMOs. The EU's legislation and policy on GMOs, based on the precautionary principle enshrined in EU and international legislation, is designed to prevent any adverse effects on the environment and the health and safety of humans and animals, and it reflects concerns expressed by skeptical consumers, farmers, and environmentalists.

USDA, FDA Sign MOU on Animal Biotechnology Regulation

January 20, 2021

The United States Department of Agriculture (USDA) and US Department of Health and Human Services signed the Memorandum of Understanding (MOU) finalizing the joint roles of the USDA and the Food and Drug Administration (FDA) in regulating products derived from animal biotechnology.

Agriculture Secretary Sonny Perdue stated the effort "clears a path to bring our regulatory framework into the 21st century." The MOU outlines responsibilities concerning the regulation of certain animals developed using genetic engineering intended for agricultural purposes. The MOU complements USDA's issuance of an Advanced Notice of Proposed Rulemaking on the Movement of Animals Modified or Developed by Genetic Engineering on December 28, 2020.

The MOU was signed on January 13, 2021, and complements USDA's issuance of an Advanced Notice Proposed Rulemaking (ANPR) on the Movement of Animals Modified or Developed by Genetic Engineering released three weeks prior. The MOU covers the responsibilities of the regulation of "amenable species" intended for agricultural purposes developed using genetic engineering. In it, USDA and FDA will both continue to implement existing laws and Acts when regulating the products. However, new roles are also highlighted such as USDA and FDA working together on a communication plan to explain FDA's role in overseeing animal genetic alterations using a streamlined, risk-based approach. USDA is also set to consult FDA when establishing a review process for the product derived by animal biotechnology.

The USDA explained in a press release that the MOU states that USDA will provide oversight of animals modified or developed through genetic engineering for human food from pre-market reviews to post-market food safety monitoring, while FDA will continue its review of intentional genomic alterations intended not just for agricultural use but for biopharma and non-heritable genetic alterations as well. The MOU intends for the transition of the FDA's pre-existing animal biotechnology regulatory responsibilities to USDA.

Notice

Government of India
Department of Science & Technology
Ministry of Science & Technology

Swarnajayanthi Fellowship

Ministry of Science & Technology
Department of Science & Technology
SwarnaJayanti Fellowships Scheme 2020-21

Government of India had instituted a scheme titled "SwarnaJayanti Fellowships" to commemorate India's fiftieth year of Independence. Under this scheme a selected number of young scientists, with excellent track record, are provided special assistance and support to enable them to pursue research in frontier areas of science and technology. The fellowship is scientist specific and not institution specific, very selective and has close academic monitoring. Scientists selected for the award will be allowed to pursue unfettered research with a freedom and flexibility in terms of expenditure as approved in the research plan. The project should contain innovative research idea and it should have a potential of making impact on R&D in the discipline.

The award consists of a Fellowship of Rs 25000/- per month in addition to the salary drawn from the parent Institute for a period of 5 years, The fellows selected along with their projects will be considered for funding by the Science & Engineering Research Board (SERB) as per SERB norms, for fellowship, recurring and non-recurring heads. The duration of the fellowship along with the project will be for a period not exceeding five years. The fellowship is open to Indian Nationals having a regular position in a recognized Indian academic/research organization. The applicant should possess PhD in Science/ Engineering/Medicine and should not be drawing Fellowship from any other Scheme of Government of India.

APPLICATION: Applications for the "SwarnaJayanti Fellowships Scheme 2020-21" are invited from eligible candidates in the format as given on DST online portal. The candidates may be required to submit further additional information as required and present the project idea before final selection. Candidates may log on onlinedst.gov.in from 11-02-2021 to access the home page of the "DST e-PMS Portal" for details and submit the application in online mode only. There is no need to send a hard copy.

The last date for submission of applications is March 31, 2021 by 2359 hrs.
This advertisement is also available at: http://www.dst.gov.in & www.serb.gov.in.

DEPARTMENT OF BIOTECHNOLOGY
Ministry of Science & Technology

DBT ANNOUNCES Fifth Call under ATGC PROGRAM

DBT Invites Proposals under Accelerated Translational Grant for Commercialization (ATGC) Program to Translate Research Leads beyond Early Stage Validation and Encourage Academia to Develop Product/Process/Application

- To Support Proposals aiming for Late Stage Validation
- To Accelerate Translation of Laboratory Research beyond Early Stage Validation
- To Bridge the Innovation Gap through Partnerships and to Provide Support System

Scheme Consists of Two Components:

Academic Lead Translation (ALT)	Academia-Industry Translational Research (AITR)
Academia Independently or in Collaboration with Other Academic Partner (s) or Industry in a Contract Research Mode.	Academia by Involving Industry as Collaborator

Who can Apply?

Academia is required to be the main applicant. Collaborations between Academia-Academia are encouraged for **ALT** and Academia-Industry are required to be applicants for **AITR**.

Industry alone or as a Primary Applicant is not eligible.

How to Apply?

Proposals are required to be submitted **online only** on the DBT ePromis web portal at https://dbtepromis.nic.in/Login.aspx . Only those proposals that are submitted as per the ATGC Proposal format will be considered. For program details and required Technology Readiness Levels (TRLs) PIs are required to visit DBT website at **www.dbtindia.nic.in/ATGC**.

For Queries, Please Contact:	Last Date for Submission of Proposals:
Dr. Sundeep Sarin, Adviser, DBT at sundeep@dbt.nic.in Dr. Sandhya R. Shenoy, Director, DBT, Medical Biotechnology Division at sandhya.shenoy@dbt.nic.in	**28.02.2021**

Centre For Biotechnology
Date: February 5, 2021
CSIR RESEARCH PROJECT WALK- IN INTERVIEW

Applications are invited for the post of RA (Research Associate) under CSIR project sanctioned to Prof. Promod Mehta, Emeritus Scientist, Centre for Biotechnology, MD University, Rohtak-124001 as per details given below.

Project Title: 'Immunological and molecular methods for the diagnosis of genitourinary tuberculosis'
Qualifications: Ph.D. Biotechnology/Biochemistry/Microbiology/Life Sciences OR minimum 60% marks at M.V.Sc./M. Pharmacy level with at least 3 years of post- M.V.Sc./M. Pharmacy research/teaching experience as evidenced from published paper in standard referred journals. Age limit: maximum 35 years.
Salary: 47,000 per month. + 8% HRA and co terminus with the project.
Duration: 3 years (initially for one year, extension subject to performance)
The candidate fulfilling the qualifications and conditions may attain the interview.
Date of interview: 26th February, 2021 at 11 A.M. Venue: Centre for Biotechnology, MD University, Rohtak-124001 (Haryana).
No TA/DA will be paid to attend the interview.
No separate letter will be issued for interview.
(Prof. Promod Mehta), Emeritus Scientist (CSIR), Centre for Biotechnology, MDU, Rohtak

University of Burdwan

THE UNIVERSITY OF BURDWAN
Rajbati, Burdwan- 713104
West Bengal
Advertisement No. 03/2020-2021
Dated: 03 February, 2021

Advertisement for appointment to the following teaching posts for the Department of (i) Molecular Biology and Human Genetics (ii) Physiology (iii) Nutrition and Public Health (iv) Electronics and Communication (v) Geo-spatial Science (vi) Psychology & (vii) Women's Studies

Applications are invited from Indian citizens for appointment of 49(Forty nine) teaching positions in the above mentioned Departments The University of Burdwan in the Pay Structure as noted against each and other admissible allowances, as amended from time to time.

No application will be accepted after 01.03.2021 (05:30 p.m.).

Applicants must have the minimum qualifications and experiences as per relevant latest recruitment guidelines and Memorandum of Government of West Bengal [No. 120 – Edn. (U)/1U-91/10, dt. 21.02.2011; No. 121 – Edn.(U)/1U-91/10, dt. 21.02.2011, No. 516-Edn(U)/1U-91/10, dt Kolkata, 16th May 2017 & 894-Edn(U)/HED 12014(21)/1/2019-UNV SEC-Dept. of HE dt. 07.08.2019.] for the Teachers in the State-aided Universities.

राष्ट्रीय पशु जैव प्रौद्योगिकी संस्थान

National Institute of Animal Biotechnology

(An autonomous Institute of the Department of Biotechnology)

Advertisement No 24/2020

Recruitment of Scientist

NIAB, an autonomous institute under the aegis of Department of Biotechnology, Government of India, is aimed to harness novel and emerging biotechnologies and create knowledge in the cutting edge areas for improving animal health and productivity. The Institute's research focus is on animal genetics and genomics, transgenic technology, reproductive technology, diseases, nutritional enrichment, and bioinformatics. The Institute aims at translational research leading to genetic enhancement of Indian Livestock species and basic research towards development of novel vaccines, diagnostics and improved therapeutic molecules for farm animals.

NIAB is looking for Scientists and visionary academic leaders with outstanding record of research accomplishments to establish strong centers of research to address the problems of livestock. Persons having effective interpersonal and leadership skills with commitment to work effectively with colleagues as part of inter-disciplinary team are required. NIAB is looking for dedicated and committed Scientists who believe in institution building and have a passion for academic excellence and quality research for filling the following vacant positions :

Positions	Pay Level	No of post	Age Limit
Scientist –G	Level 14 as per 7th CPC	1 (UR)	Not exceeding 50 Years
Scientist -F	Level 13A as per 7th CPC	1 (UR)	Not exceeding 50 Years
Scientist-B	Level-10 as per 7th CPC	1 (UR)	Not exceeding 35 years

WOMEN SCIENTISTS FULFILLING THE REQUIREMENTS ARE ENCOURAGED TO APPLY
Last date for submission of online applications is 25-02-2021 and submission of hard copies is 06-03-2021. For more details, please visit NIAB website www.niab.org.in

birac
Ignite Innovate Incubate

TiE DELHI NCR
FOSTERING ENTREPRENEURSHIP

BIRAC-TiE announce the launch of

BIOTECH WInER Award

Women In Entrepreneurial Research

4th Edition

WHAT WE PROVIDE

- 15 selected women entrepreneurs will receive seed money of INR 5 lakhs each
- Access to expert mentor network of TiE & BIRAC
- One year membership of TiE Delhi NCR
- Showcase opportunities at TiE
- Access to TiE Startup Accelerator Programme
- Opportunity to go through an intensive Accelerator Programme

HOW TO APPLY

To submit your application, please click on the link below:

https://forms.gle/95EYomArjJqupCRE7

WHO CAN APPLY

A woman entrepreneur in the area of Life Sciences/ biotech/ pharma with an exciting entrepreneurial idea.

The woman entrepreneur should be:

- An Indian citizen (holding Indian passport)
- One of the promoters of the Indian company* working on the above idea and in existence for less than 10 years as on date of closure of call
- The Principal Investigator of the project/idea being pitched for

**A company is considered as Indian company if minimum 51% of the capital in it is beneficiary owned by resident Indian citizens and/or Indian Companies, which are ultimately owned and controlled by resident Indian citizens*

3 FINAL WINNERS (POST ACCELERATOR PROGRAMME) WILL BE AWARDED

INR 25 LAKHS EACH

IMPORTANT DATES

Submission Starts	Submission Closes
29th Jan, 2021	15th Mar, 2021

For any Queries, please contact:

shaila@delhi.tie.org | sped01@birac.nic.in

International Conference on Biotechnology for Sustainable Agriculture, Environment and Health

XVII Convention of BRSI

(BSAEH-2021)

ISSN: 2454-6968
RNI No. UPENG/2013/54102

April 4-8, 2021 Jaipur

Details: http://brsi2020jaipur.in/

Conference will be held in Hybrid mode (Physical and Virtual)

The event will be jointly organized by the MNIT, Jaipur; CDC India, Jaipur, BISR, Jaipur and NIT-Uttarakhand in association with the International Solid Waste Association (ISWA), The Institute of Chartered Waste Managers (ICWM) and B Lal Institute of Biotechnology, Jaipur. This will be supported by the International Bioprocessing Association, France; Centre for Energy and Environmental Sustainability (CEES)-India and Amity University, Jaipur. The event will be held at BISR, Jaipur. Prof TP Singh, Prof AB Gupta and Dr Vivek Agarwal are conference chairs. Dr V Vivekanand is the convener of BAEH-2020 and Dr P Binod, COE, BRSI; Dr Krishna Mohan, BISR, Jaipur and Dr B Lal, BIB, Jaipur, Dr Rakesh Kumar Mishra, NIT-Uttarakhand are its co-conveners. Details can be found at http://brsi2020jaipur.in/