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NEWSLETTER

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Galenisys wins another vaccine related contract



By Steve Biddulph

Fellow of Royal Institute of Microbiology. Board level pharma experience. QSM and Aseptic Manufacturing & Control Expertise

"Galenisys is delighted to announce that we have again been retained by a leading multinational pharmaceutical company to assist them in their campaign to further improve procedures & precautions in aseptic & sterile vaccine production & QA.

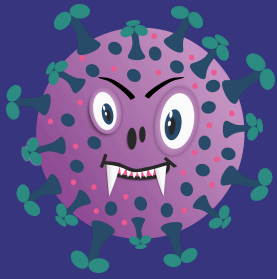
Sterile product manufacture, asepsis and control is a specific area of expertise for Galenisys.

We have experts who are recognised throughout the industry and who have worked at both shop floor and strategic levels to ensure that sterile product quality is assured, maintained, and is in compliance with the requirements of the world's leading regulatory agencies.

We welcome this additional endorsement of our core area of expertise "

Steve Biddulph MD





Viruses (should still) grab the headlines



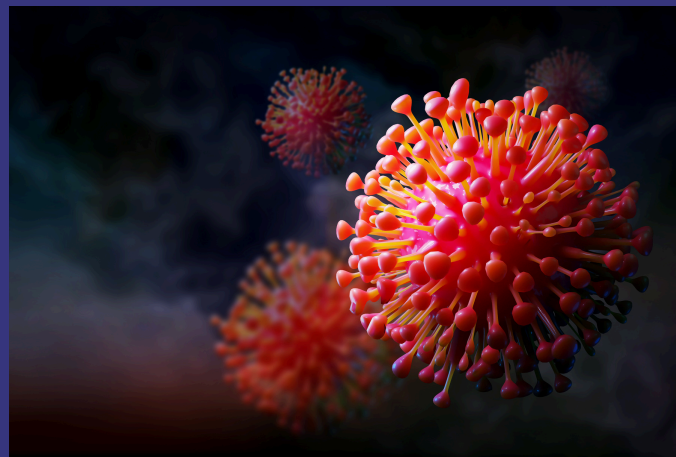
The Editor

Coincidentally, just the same day (May 5th) as I was putting away into storage my remaining masks, surgical gloves, and COVID test kits; the World Health Organisation announced “the end of the COVID-19 as a Global Health Emergency”.

What's the global mood now the worst seems to have passed? Can we “move on” and resume having fun?

- Is it all over? Might we need our PPE again?
- Have the lessons been learned by Governments & Health Authorities?
- Is anybody working to prepare for another malevolent virus causing a deadly pandemic?

Firstly. Is it all over?



The headlines of the media echoed the positive part of the WHO message, the end of the Global Emergency of cases on a steep downward trend.

But still causing “a (known) death every 3 minutes” The disease is estimated to have cost some 20 million lives worldwide, using excess death calculations (three times the official figure because of underreporting).

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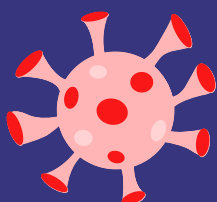


The pandemic may be over but the sub variants of Omnicrom are still around (600ish to date). Whereas this may be expected in a highly vaccinated population, some variants still give cause for concern.

Arcturus or X BB1.16 is the most contagious (ie transmittable) of these identified sub variants. Having first been detected on the 23rd of January 2023 it had spread to (at least) 34 countries by end April.

It caused a 13 fold increase in COVID cases in India in March, and represented 5% of cases in USA & Australia, and 12% in Singapore. It has also arrived in the UK and in France. It provokes the usual symptoms – fever, cough etc - but also conjunctivitis, particularly in children.

The WHO placed it on the list of “variants of interest” in March, & although it must be stressed that it is not a great cause of concern; it is a useful reminder that this virus is still with us.



Learning lessons??



People are understandably wanting to get back to their normal happy lives & make up for the deprivations of the lockdowns. The climate is not conducive currently to learning lessons or revisiting the painful moments. However, given the millions of deaths, countless bereaved families, & economic damage; it's prudent that now - at the end of this emergency - governments & health authorities do investigate what they did well and did not do well, to avoid or at least mitigate likely future health catastrophes.

One government in particular want to move on and then sure that its citizens have their normal happy lives without a post-mortem even given the origin of the pandemic in Wuhan. However it seems there will be no public inquiry in China into how officials handled the outbreak, or the harsh and protracted lockdowns in city after city.



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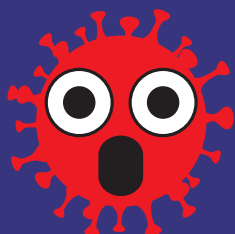


There will be no open investigations into where the virus came from, or whether better safety precautions might have prevented the global disaster we all participated in. Rather the issue is now summarised in the statement that the country “won a major and decisive victory over COVID-19”.

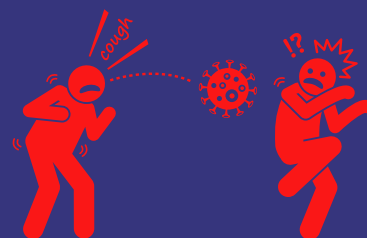
In the absence of these investigations two recent books by Chinese authors:
“Deadly Quiet City” by Murong Xuecun; and “Wuhan Diary” by Fang Fang,

are particularly valuable in providing an essential precursor of any investigation, namely granular accounts of how COVID emerged late in 2019 and how the Chinese government responded, and are recommended reading.

(Since publication the authors and other independent journalists have suffered harassment, imprisonment, or have fled abroad).



What else are viruses doing?



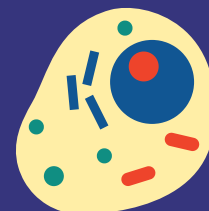
We are of course surrounded by viruses. One which is currently a particular problem for tame and wild birds is the H3N8 avian influenza strain. According to the World Health Organisation it has claimed the first human victim. Human bird flu cases usually arise through exposure to infected live or dead poultry, and this appears to be the case for the Chinese victim although the World Health Organisation has said it is still unclear what the exact source was.



Since identification the strain has been detected in wild birds and poultry flocks in various countries including the UK.

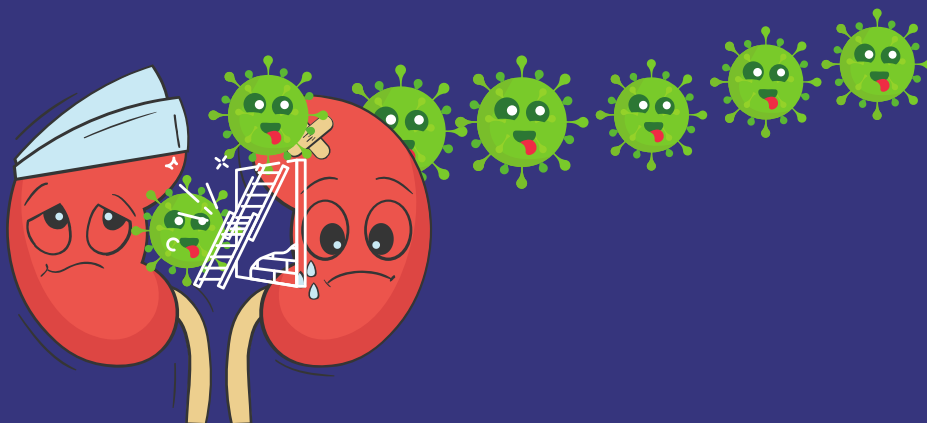


THE HUMAN CELL ATLAS PROJECT



The Editor

“Virus particles escaping from a kidney cell”



An intriguing colour photograph with this title made me tear out and keep a lengthy article in the Economist (11th March). Coming back to it six weeks later I was intrigued to read for the first time about the existence of

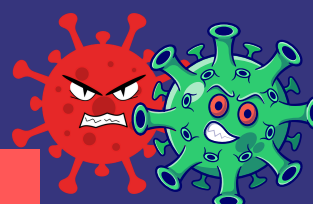
THE HUMAN CELL ATLAS PROJECT

I doubt whether many other people have heard of it either.

Here’s a simple analogy: The Human Cell Atlas Project aims to map the cells in the human body in a similar way to the Human Genome Project provided the exhaustive map of human DNA.

But the Human Cell Atlas project is likely to have a least as much medical importance as the genome project had & has.

It’s Mission is “To create comprehensive reference maps of all human cells—the fundamental units of life—as a basis for both understanding human health and diagnosing, monitoring, and treating disease”.



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Given the average human body has some 3.7 trillion cells the project is not going to provide a location of all of them. (Google maps doesn't show every blade of grass). However, although not showing every cell, this Atlas will identify and characterise every type of cell, where that cell type is found in the body, within which organ, or even within which tissue within an organ, and the whereabouts within that tissue. It's clearly a big job, and no one knows how many **types of cells** there are!

The project began in October 2016 and since then has signed up more than 2900 researchers from over 1500 institutes in 94 countries (which helpfully provides for varied ethnicity). Surprisingly the project was founded and run by two determined women with plenty to do in their day jobs at the Wellcome Sanger institute near Cambridge UK and Genentech a biopharma firm near San Francisco.

Farther & Faster - Since inception over 14,000 samples from nearly 10,000 donors have been analysed and the resulting data from 120 million cells have been logged (progress is exponential - this number doubles every half year).



Classes of technological methods involved in the Cell Atlas Project include tissue imaging, histology, transcriptomics, genome and epigenomics. These classes subdivide into 100 categories (!) with techniques like magnetic resonance imaging, nucleosome occupancy, and methylome sequencing. Suffice to say, it's complex, ingenious, and pioneering; as well as beyond most of us.

But it will be very important for us and for our descendants as the ultimate purpose of the exercise is to **improve human health**.

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Separate Atlas Volumes have already been created and made a difference. For example, in understanding cystic fibrosis. Previously researchers thought that they knew which of the lung cells were expressing for broken versions of a gene called CFTR. However, the Cell Atlas showed researchers a rare and hitherto unknown type of lung cell is the culprit and this discovery is now changing the direction of cystic fibrosis research.

Similarly, Guts Cell Atlas researchers have discovered entirely new cell types which might thus become targets for drug treatment involved in inflammatory bowel disease.

Now scientists working on the Cancer Cell Atlas can predict from mRNA profiles whether or not a case of melanoma will respond to immunotherapy.

The founders of the Human Cell Atlas Project, Drs Regev and Teichman are particularly proud of the atlas's role during COVID-19.

Once the relevant proteins which the virus invades, were identified, researchers around the world were able to go through the Atlas looking for these cell types & thus pinpoint tissues (other than the respiratory tract) which would also probably be harmed by the infection, such as the liver heart and kidneys.

In the future the cell atlases used for eg:

- identifying the best candidates for cell engineering (the employment of genetically modified cells as therapies).
- the mass screening of potential drugs to see their separate effects on particular cell types.
- and the design of experiments using extracts of actual organs - experiments that would not be possible on people.

The Editor

