

ISPE UK Affiliate Response to the Covid 19 crisis

Project remit – To provide a database and point of contact so that those needing Pharmaceutical knowledge, services, equipment and consumables in their response to Covid 19 can be quickly put in touch with ISPE and other contacts that can provide this.

Background

There are many projects being undertaken to alleviate and tackle the Covid 19 pandemic such as ventilator and vaccine development and manufacturing, antibody therapeutics, viral testing, API manufacture, oxygen supply, contamination control and healthcare consumables. ISPE is set up to share Pharmaceutical Knowledge. Across our 800+ UK members, we have the widest breadth of people who are used to serving the healthcare industries and willing to share their expertise and resources. Some of those developing Covid 19 projects have no real ideas of how their non healthcare knowledge can be so different in healthcare. It is also true that the normally conservative approaches in healthcare need to be challenged at this time. Velocity has so much more value in saving lives than great mounds of paper, but the risks taken need to be explicit and sensible. We must apply GMPs.

It therefore seems obvious for the ISPE UK Affiliate to set up a database of resources and knowledge that is searchable and also has a point of contact to save small but precious time to get some of these Covid 19 applications in the field to save lives.

Our normal modus operandi is an informal network. We share Pharmaceutical Knowledge and do not wish to promote any particular solution or provider over any other as a non-profit organisation looking to improve the greater good. The 2019 GDPR regulations also protect personal confidentiality and we need to align to these. Such a database and sign posting needs to try to adhere to our principles and data handling policies, but it needs to be as open access as possible. So, particular attention needs to be paid to this balance, the desire for confidentiality versus utility.

Project Deliverables

A simple, searchable database using Google docs that links needs with ISPE contacts for individual use with an optional ISPE volunteer to talk through and assist people with the right terminology in the database and personal networks to assist those on the front line of Covid 19 projects. ISPE volunteers will be gate keepers between what assistance is on offer in the database which is public and the personal contact details of members which will remain confidential, except to those in need of specific ISPE help. The ISPE volunteers provide the link on a one to one basis. This is our balance to protect privacy of our members. Our over-riding intention is to assist other's Covid 19 initiatives with sound knowledge.

Project Timescale

27 March 2020 – Letter to members informing them that we will respond to the Covid 19 crisis. Done.

W/C 30 March - Generate and send out form for members to complete. Inform other Professional Organisations of our activities.

Members respond with completed forms and this is compiled into the database with editing to improve searchability.

As soon as there are 20 or more entries, put the content on the ISPE UK website to prompt others to respond and to allow testing.

W/C 12 April – Go live with public, view only access of the offers in the database to Companies, Academic Institutions, Professional Organisations and Individuals with a dedicated e mail address, covid-response@ispeuk.org to allow ISPE volunteers to made the links to those offering help.

Further entries can be added and improvements can be made in real time. This would not normally be in scope but we need to continually improve the data expeditiously. The ISPE web site will contain the most recent view only version. It will not be static.

Project Steering Team

Pat Drury – ISPE UK Chair.

Jon Youles – ISPE UK Vice Chair and ISPE UK member database

Dr Peter Dodd – Project Manager.

Adam Hawthorne – IT and ISPE UK Professional Liaison.

Nick Kesterton – IT Systems.

Philippa King Smith – ISPE UK Communications.

Lynn Bryan – ISPE European Advisory Committee Chair and Regulatory.

Contact will be virtual via email except that major decision making and reviewing will be by video link in our normal manner.

Project Resources

Volunteer time.

If there is a need for small amounts of money, this can be organised by ISPE UK. All of the steering team are ISPE UK Board members.

Project Constraints

The project needs to be delivered from a standing start as quickly as possible. Time is the largest constraint. We need to recognise that we should not advertise whilst all the technical information offered can be made as open source. It needs to be secure and therefore the definitive version needs to be hosted on our website and/or the websites of those partners that we trust. The database specific request e mail address covid-response@ispeuk.org will be answered by ISPE volunteers. This is to protect the privacy of contact details unless there is a matched request. There will be a small delay while the ISPE volunteer puts the requestor and the supplier together. There is no contingency if any volunteers are laid low by Covid 19.

The ISPE UK Board will decide when and how the database is withdrawn from use. It may be something that becomes worthwhile going forward with permission from the contributors to continue to be part of it.

Acceptance Criteria

Launch of database and point of contact to open search offers with a referral on covid-response@ispeuk.org to make the contact links plus one month of operation.

After launch, monitor the ongoing operation of the database and point of contact so that the purpose is achieved. This project will be handed over to the operating team. (The operating team may be similar to those involved during the project but not necessarily so.)

Deviations

Any ISPE board member can raise a deviation which needs to be sent electronically to the UK Chair and the Project Manager. The Project Manager will form a log, investigate the deviation, apply corrective actions and inform the Steering Team of the results. Using electronic means, this can be kept close to real time by use of shared documents and alerts. It is not anticipated that this will occur often. If it does happen often, the Project Manager

will appeal for assistance. ISPE members can communicate with any ISPE Board or Regional Committee member.

Increases in scope

Our project will be communicated to ISPE Ireland, where there is a significant Pharma sector and potentially other ISPE Affiliates as well. It may be that they wish to join. Whilst welcome, this will be addressed as Changes of Scope because we cannot second guess how they would wish to join in.

Our project will also be shared with other UK Professional Organisations, and likewise, there may be a request to join. Again, this is welcome and would be a change of scope. It may be that one of these could take the lead at hosting. ISPE UK is not precious at keeping this in house because our priority is to expedite the response to tackle Covid 19 but our liability needs to end on any transfer out of ISPE UK.

Changes of scope must be agreed by the Steering Team by virtual contact.

Benefit of this database over the WWW

People involved with Covid 19 projects do not always understand the healthcare sector and the absolute importance of treatment efficacy, patient and manufacturing safety. ISPE members do. The internet is full of many solutions but if the correct search is not initiated, who knows what any search will come up with? There will be time wasted. Therefore, our database is worth at least several hours of effort to each project. It might even prevent blind alleys and hence it is of great worth to society at this time.

Dr Peter W Dodd 31 March 2020

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