Medicines & Healthcare products Regulatory Agency

Board Meeting

NIBSC HIGHLIGHTS FOR FIRST QUARTER of 2018/19

22 October 2018

Issue/ Purpose: To provide the Agency Board with a summary of NIBSC highlights against its activities in the first quarter of 2018/19
Summary: The document provides a summary of key achievements by NIBSC in the first quarter of 2017/18 and also highlights some areas that will be continued as we progress through the reporting year. There are some references to progress in Q2 where known but at the time of writing this we were just commencing the Q2 report updates from objective owners.
Resource implications: **N/A**
EU Referendum implications: Some implications to NIBSC activities mostly in the area of product control work – details provided in the report.
Timings: The report covers the quarter from April 2018 to July 2018 inclusive.
Action required by Board: To note activities achieved.
Links: None
Author(s): Marie Donatantonio
Which of the five themes in the Corporate Plan 2013/2018 does the paper support? All **If relevant, which Business Plan strategic activity does it support?**
CET Sponsor: Christian Schneider

NIBSC Highlights from Q1 2018/19

It has been a good start to the year with almost all activities on track.

Standards

Under the category of developing new standards and reference materials, outlines of proposed projects for new or replacemernt standards were presented to the NIBSC Annual Standards Review meeting and all standards that are to be presented to WHO's Expert Committee on Biological Standardisation (ECBS) in October 2018 are on track. In addition, the Standards Programe Board monitors new projects in the pipeline and so far in the first quarter five new projects projects were endorsed, four for 1st WHO International Standards (IS) and one for a new CE-marked multiplex in-vitro diagnostic (IVD). Four new projects have been endorsed in quarter two but details not yet reported on.

Biosimilars

There has been some good work in promoting the role of biological standards in the biosimilars regulatory framework with staff attending the Parenteral Drug Association (PDA) pharmacopoeial conference in Vienna to discuss the BP/NIBSC/MHRA strategy for biological pharmacopoeial standards. Also a review was published in American Pharmaceutical Review entitled "International Standards to Support Biotherapeutic Monoclonal Antibody Products Quality and Consistency over Time: Learnings from the Development of the 1st WHO IS for the Biological Activities of Rituximab".

Influenza

The work to support timely supply of influenza vaccines involved reagent preparation and calibration in June for the northern hemisphere vaccine campaign. Freeze dried candidate vaccine viruses were made available with two replacement fills and twelve new viruses added to the catalogue, six being wild type strains and eight high growth reassortants. Staff from the influenza group took part in the joint meeting held in June between Industry, WHO and the Essential Research Laboratories for influenza, of which NIBSC is one.

More recently in September there has been a decision made at the WHO influenza strain selection meeting in Atlanta, USA for a single strain changes to be made. This will raise interest in candidate vaccine viruses (CVV) available at NIBSC because currently a CVV produced at NIBSC is the only WHO recommended CVV for the new vaccine component. New reference reagents will also be required and work will now commence to develop these.

There was recent interest in the role of NIBSC in making flu vaccines. Dr Othmar Engelhardt, Principal Scientist in the Division of Virology, flu section, gave an interview for a radio programme produced by The Naked Scientists, on the Spanish Flu epidemic, incorporating an exploration of the field of vaccines in the past 100 years. The show was broadcast in Cambridge on Sunday 23 September and is available as a podcast. The link to the specific work on influenza vaccines can be found at: https://www.thenakedscientists.com/articles/interviews/how-are-flu-vaccines-made

Polio

Support for polio eradication continues with a collaborative study for Next Generation Sequencing (NGS) of Oral Polio Vaccinee (OPV) presented at the Standards Review meeting at NIBSC in May and the Sabin Inactivated Polio Vaccines (IPV) project now submitted for establishment at ECBS. All projects for vaccine development are proceeding according to expected timelines.

In September there has also been an important step forward for the future of containment of hyper-attenuated poliovirus strains. In response to questions and submissions by the NIBSC team to the WHO Polio Containment Advisory Group (CAG), the group have recommended that, subject to national approval, hyper-attenuated S19 strains, can be handled outside of GAPIII (Global Action Plan) containment requirements. This opens the door for widespread use of the strains as reagents and vaccine seeds. An excerpt from the full report states, “The CAG … concluded that the strains (S19/S2P1/N18S and S19/MEF1PI/N18S) can be used outside of the containment requirements of GAPIII for purposes stipulated in the submissions made, e.g. Inactivated polio virus (IPV) production, rat neutralization IPV potency assays, human serum neutralization test for poliovirus antibody determination and potency testing for immunoglobulin (human) lot control and release.”

Emerging Pathogens

Development of reference materials for emerging infections has involved work on the 1st IS for Zika antibody, now submitted for establishment by ECBS in October; participation in a Middle East respiratory syndrome-related coronavirus (MERS) standardisation meeting in Korea; sourcing of material for the 1st IS for Dengue antibody; and 10 new IS presented at NIBSC Standards Review for the serology and diagnostics of emerging pathogens. Also a meeting with Nigeria Centre for Disease Control (CDC), Federal teaching Hospital Abakaliki and PHE took place at NIBSC to set up collaboration for sourcing of material for emerging pathogens reference material.

Medicine control testing

With the risks that Brexit poses to the future of control testing at NIBSC various objectives this year were targeted at increasing the strength and breadth of biologics testing capability. Good progress is being made in supporting the ability to identify all opportunities for batch release testing with an up to date record being maintained of all contact with batch release customers so that updates and opportunities are shared in order to promote the testing capabilities where possible. In addition, flexibility of resources to match any new opportunities is more important than ever and level of workload is being monitored across all areas. There has been regular input into the agency Brexit discussions ensuring that the monitoring of effects of Brexit on batch release is fed in quickly, and a business continuity exercise is underway to assess the impact on control testing as well as on standards distribution.

Supporting Innovation

In supporting innovation and future development, there are several exciting areas of work. Early collaborative studies and pilot preparations to develop

standards for Shigella flexneri 2ª and Shigella sonnei are going well, as well as for group B streptococcus reagents. Good progress has also been made in the support for microbiome-based therapies with next generation sequencing completed for all commercially available microbiome standards and the gut microbiome standard created at NIBSC. Reference materials have also been prepared to support the standardisation of lung microbiome techniques for a multi-centre study led by PHE analysing how the lung microbiome may influence treatment of chronic obstructive pulmonary disease (COPD). Analysis is also taking place with Warwick Medical School to see if microbiome interventions can be used to cure Ulcerative Colitis and Crohn's disease.

Work is taking place to establish and evaluate novel paradigms and approaches for evaluating or predicting immunogenicity and immune-toxicity of Biological therapeutics in man with the initiation of a pilot for the infection of human immune system mice with Plasmodium falciparum using two different mouse models (DRAG and NBSGW).

In supporting the agency in combating suspected illegal medicines, a business case is being prepared for replacement of the old mass spectrometer to help in continuing this work. There is however on-going work analysing different exhibits, including four suspect falsified vaccines and four enforcement samples and also development of workflows for biosimilar analysis.

Advanced Therapies

In Advanced Therapies, £2.1 million grant funding was awarded to continue support of the development of the EU Tissue and Cells Directive (EUTCD)-grade cell line programme. Further stages of funding will contribute to the further characterisation of these EUTCD-grade cell lines and make sure they continue to meet the needs of product developers. With the continued funding, the UK Stem Cell Bank will now seek to further characterise the EUTCD-grade cell lines using whole genome sequencing and cancer panel screening to detect tumour-specific genomic modifications.
There is also work to develop a strategy for the UK Stem Cell Bank to ensure its future and updates are being provided to CET on this.

The area of Cancer Gene Therapy has been delayed due to the loss of the lead member of staff. The plan for this work has therefore been revised but the target is currently not on track until we find a person with the right credentials.

Financial Sustainability

The long-term financial sustainability of NIBSC is key at the moment with additional uncertainty in several aspects. Development of the Grants Office is therefore important in order to generate income and the Grants Manager is progressing well to drive the volume and value of grant applications. There is also better highlighting of relevant new calls to NIBSC scientists, providing more comprehensive information internally on grant funders' requirements, and one-to-one support to assist individual scientists with applications, along with improved information available on processes to follow. It is also key to enhance NIBSC's profile with stakeholders and customers and the

communications plan is being monitored closely by the NIBSC Communications Management Group (NCMG). Linked with financial sustainability is also the long-term suitability of the facilities at NIBSC and the agency Accommodation Review in Q1 will help consider what needs to be done. This will include looking at the long-term replacement plan for the standards production facility as well as ensuring that all aspects of the site security projects are on track and suitable for the work carried out at the site.

Introduction of new systems and initiatives

There is continued review of new systems and initiatives to ensure they are effective. There is continued review following the introduction of GS1/PEPPOL successfully at the start of the year to ensure all is working correctly and the benefits are realised. Other programmes of work are the follow-up to the introduction of the new GDPR regulations in May; development of the H&S strategy for the agency; and implementation of the staff engagement plan following last year's staff survey for which an additional survey was carried out at NIBSC to dig into some of the areas and understand better staff concerns.

Organisational items

Following the retirement of the Head of Biological Services, that division has now been combined with Technology, Development and Infrastructure to form a new division called Analytical and Biological Services (ABS) Division headed up by Marc Bailey. The review of Operations continues with an interim strategic lead in post. The Head of Viral Vaccines and Head of Corporate Affairs are also in an interim stage whilst review of those areas takes place.

NIBSC Director and Senior Management Team have been heavily involved in the Agency Operational Transformation programme. Part of this has been the input to the Science and Research Workstream which is being led by Dr Christian Schneider and includes a review at its half-way stage of the current 10 year 2013 – 2023 Science Strategy to ensure it is fit for purpose in line with the changing external and internal environments.