The Global Language of Business

HUG-15-M5

GS1 UK Healthcare User Group Meeting Minutes 8 Sept 2015

Present

Owen Inglis Humphrey	Department of Health (Group Chair)
David Weatherby	GS1 UK (Group Facilitator)
Andrew Crosbie	MHRA
Barbara Fallowfield	BIVDA
Glen Hodgson	GS1 UK
Jackie Pomroy	NHS South of England Procurement Services
Judie Finesilver	Commercial Medicines Unit
Judith Mellis	ABHI
Mandy Hollis	Milton Keynes Foundation Trust
Michael Sinclair	Dorset County Hospital Trust (by phone)
Natalie Bateman	techUK (by phone)
Paul Fownes	NHS Supply Chain
Paul Glanville	NHS Supply Chain
Terence O'Kelly	Scottish Government
Virginia Minogue	NHS England

In Attendance

Frankie Wallace	Department of Health
Juliette New	GS1 UK
Mike Kreuzer	ABHI (by phone for item on EU EDI only)
Tim Brown	GS1 UK (for item on GS1 UK Conference 2016 only)

Apologies

Andy Smallwood	NHS Wales Shared Services Partnership - Procurement Services
Dr Sara Davies	Scottish Government
Jenny Gough	Molnlycke
Rachael Hughes	3M
Shiraaz Essop	NHS Supply Chain
Steven Gore	HSCIC

Agenda

1. Welcome and competition policy
2. Apologies for absence
3. Introductions
4. Minutes and matters arising
5. Update on EU UDI Regulations and implications for the HUG
6. GS1 UK Conference 2016 – venue and dates
7. Demonstrator Sites and links with the HUG
8. NHS Supply Chain and GS1 and PEPPOL adoption
9. GS1 Mini Case Studies
    a. Everyone to bring an idea however small
10. Identifying staff using GS1 standards
11. Update on EU FMD Regulations and implications for the HUG
12. Any Other Business
13. Action Items and Next Steps
    a. Dates and Agenda items for next meetings

Minutes

Item 1 Welcome and competition policy
Dave Weatherby drew the attention of the meeting to the GS1 Competition policy

Item 2 Apologies for absence
Dave reported that apologies had been received as shown above

Item 3 Introductions
Those attending introduced themselves

Item 4 Minutes and Matters Arising
The minutes were approved for publication

Item 5 • Update on EU UDI Regulations and implications for the HUG
The EU UDI draft regulations will be part of the more general Medical Device Regulations (MDR) a draft of which is currently being worked on and is expected to go to review by the European Commission, the European Council and the European Parliament in October 2015. This tri-alogue review is expected to lead to the adoption of the MDR in Q1 or Q2 of 2016.

The UDI elements of the MDR are not contentious but the current document has some inconsistencies and elements which the medical device industry is concerned to correct and clarify.

The US FDA UDI regulations, which are already in effect, were contained in a dedicated document in contrast to the EU approach of a broader overarching document on medical device regulation of which UDI is merely a part.

The EU UDI regulations will include a provision for an EU database of devices similar to the FDA's GUDID. The public will have access to core data in the database. Medical device suppliers will be required to maintain accurate product information in this database. The technical design of the UDI database must ensure permanent accessibility on information stored in the UDI database and allow multi user access and automatic up and downloads of this information. Device suppliers and care providers will be required to provide information to patients about the products used on them.

Medical device suppliers will be required to keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any amendments and supplements for at least 5 years, or 15 years in the case of implantables, after the last device has been placed on the market

The meeting expressed concern that data on a medical devices was only required to be available for a maximum of 15 years noting that where a device is implanted in a child then information about that device might be required more than 100 years later.

The US has authorised GS1, HIBCC and ICCBBA as agencies for issuing UDIs. It is expected that the EU will also designate at least these same three agencies. The designated agencies must undertake to manage the assignment of UDIs for at least ten years from the date of designation. The European Council will promote interoperability between the different UDI systems. GS1 already has a Memorandum of Understanding with ICCBBA about the appropriate use of GS1 and ICCBBA standards.

The NHS as a purchaser of medical devices has decided to require its suppliers to use GS1 standards in preference to HIBCC standards. In time this will mean that products that are not GS1 compliant will not be purchased by the NHS. Medical device suppliers who currently use HIBCC standards and wish to continue to sell to the NHS will need to either convert to GS1 or support GS1 standards in addition to HIBCC.

Mike Kreuzer notes are attached.

ACTION: David Weatherby to draft a note from the HUG to be sent to Mike Kreuzer expressing the need for data about medical devices to be held for 100 years.

Items 6 GS1 UK Healthcare Conference 2016 and AGM
Tim Brown explained the plans for the GS1 UK Healthcare Conference for 2016 which will be held on Tuesday 12 and Wednesday 13 April 2016 at the Radisson Blu Edwardian Heathrow. Lord Prior, Parliamentary Under Secretary of State for NHS Productivity, has confirmed that he will attend on the 2nd day A PDF of the slides he presented is attached.

He also explained that the GS1 UK AGM will be held at the conference centre at 30 Euston Square (https://30eustonsquare.co.uk/) on the 12th November at 4.30pm followed by a GS1 UK briefing and a networking buffet and drinks. As previously agreed the next HUG meeting in November will be held at the same location as the GS1 UK AGM and immediately before it. More details to follow.

ACTION All to add the GS1 UK conference and the GS1 UK AGM to their diaries.

Item 7 Demonstrator Sites and Links with the HUG

Owen reported that the 12 trusts had been shortlisted. Review meetings were being held with all 12 and he had been impressed by the enthusiasm shown by those sites already visited. Benefits that had been put forward around the tracking of place, patient and product included: patient level costing, managing person versus clinical preferences for equipment, safety recall, and improved surgery throughput and better patient records.

The shortlisted sites will produce their propositions in the form of business cases by mid November and a decision on which 6 will be selected as the final demonstrator sites in mid December.

The selected demonstrator sites will participate in a DH steering group for the board level sponsors. In addition the DH plans a working group for the Trust programme managers, DH work stream leads and GS1, chaired by the DH.

There was some discussion on the relationship of the HUG and the demonstrator sites. It was recommended that the chair of the DH working group and a revolving representative from one of the demonstrator sites should attend the HUG

ACTIONS Owen to capture examples of benefits from the business plans and cases and make available
Owen to progress the relationship of the HUG to the demonstrator sites
Terry to make available a document on the compelling case for product tracking

Item 8 NHS Supply Chain and GS1 and PEPPOL adoption

Paul Glanville summarised NHS Supply Chains current plans to adopt GS1 and PEPPOL standards. He explained that NHS SC had split the eProcurement plans into the following four major projects:

- GS1
- PEPPOL
- eDC Gold
- Catalogue Development

Plans for these major projects are expected to be signed off by the NHS SC board before the end of 2015.

A PDF of Paul's presentation is attached.
Please note this PDF is for HUG members only and is NOT to be distributed further.

Item 9 GS1 Mini Case Studies

Owen again made a request that all HUG members should provide a short description of some work recently completed or currently being undertaken.

The following notes were from the minutes of the HUG July meeting.

Barbara	Provide one or more case studies from a BIVDA member who had recently adopted GS1 standards
Rachael	Contact other suppliers to create a joint paper on issues in implementing GS1 standards and ways of addressing them, including who should own GS1 compliance in a supplier
Mike	Note on issues of GS1 compliance within Dorset including integration the wider community
Mike	To make contact with the Federation of Informatics Professionals in Health and Social Care to make them aware of the relevance of GS1 standards to their work and the activity of the HUG
Jackie	Note from a clinical lead at Portsmouth on the clinical benefits of GS1 standards
Andy	Note on the GTIN recall notice, what was done and why and how this might be extended in future
Dave	Request Jonathan Brown, Solution Partner Manager at GS1 UK, to ask solution providers for case studies
Dave	Work with GS1 UK marketing to produce a diagram/mind map with links to relevant GS1 documentation
Judy	To provide diagram as possible link to GS1 documentation

ACTION	All to provide mini case studies. Dave to resend the template for mini case studies
Glen	Contact Joe McDonald regarding the CCIO Summer School and possible input about the relevance of GS1 standards to their work
Owen	Contact John Williams at the Royal College of Physicians concerning the relevance of GS1 standards to their informatics activity and the work of the HUG

Item 10 Identifying staff using GS1 standards
This item was postponed till the next meeting

Item 11 Update on EU FMD Regulations and implications for the HUG
This item was postponed till the next meeting

Item 12 Any Other Business
There was no other business

Item 13 Actions and Next Steps
The next meeting of the HUG will be a face to face meeting at 14.00 to 16.30 on the 12 November at the conference centre at 30 Euston Square, London. The HUG meeting will be followed by the GS1 UK AGM.

There is no HUG meeting in October.

Suggested agenda items for the next meeting

- Direct part marking
- Presentation from techUK on Interoperability

The meeting closed at 16.35