U.K. Radiopharmacy Group

NEWSLETTER
2013 Q3

UKRG INITIATIVES

UKRG Terms of Reference and business plan

UKRG has updated its ToR, to improve the governance arrangements for the UKRG Committee, and business plan. The revised document will soon be available on the UKRG website. Current business plan objectives are as follows:

9. UKRG Business Plan

9.1 Short Term Objectives (1 year)

9.1.1 Compilation and updating local network lists. Data will be supplemented by the most recent BNMS department survey.
9.1.2 Provide national advice to stakeholders following the implementation of EU directive 2010/32/EU on the prevention of sharps injuries
9.1.3 Ensure that radiopharmaceutical staff are included in the career development programme for the Modernising Scientific and Pharmacy Careers initiatives.
9.1.4 Implementation of new guidance documents when they are finalised.
9.1.5 Establish a framework for manufacturer audits in conjunction with stakeholders.

9.2 Long Term Objectives (3 years or on-going)

9.2.1 Lead on the issue of QP training of radiopharmaceutical staff within the NHS and academia.
9.2.2 Introduction of Ga68 based radiopharmaceuticals into clinical practice
9.2.3 Populate SNOMED CT with radiopharmaceutical data set.
9.2.4 Facilitating appropriate implementation of the ARSAC strategic report
9.2.5 Collate "The Problems Associated with Radiopharmaceuticals Database" in conjunction with the medical assessor of the BNMS. To publish these reports on a quarterly basis; advising the MHRA and/or Industry where appropriate
9.2.6 To further develop local networks and establish funding for appropriate activities eg audit
9.2.7 Reviewing the implications of withdrawal of products from the market.
9.2.8 Undertake manufacturer audits as required
9.2.9 Update the sections of the Guidance documentation and publish on the UKRG website

Provision of Radiopharmacy Services in the UK

Readers may know that UKRG has previously published Guidelines on the Provision of Radiopharmacy Services in the UK (March 2012), copies of which are available on the website at this URL: http://www.bnms.org.uk/ukrg/guidance-notes/.

At the last UKRG Committee meeting held in July it was agreed that these Guidelines should be reviewed and updated, to strengthen the guidance in the light of increasing pressures to restructure departments. Once the revised document has been agreed it will be made available on the website and publicised in the Newsletter.

GMP Inspections of Licensed Units

The MHRA is to publish a Q&A document on GMP Inspections, to help Licensed Units understand the regulator's approach to assessing compliance with EU GMP. UKRG, together with the Pharmacy QA Committee, have commented on the draft of the Q&A document. The MHRA is producing a final version which it is expected will be published later in the year.

Re-sheathing of needles

The UKRG guidance on the implementation of the Health and Safety (Sharps Instruments in Healthcare) Regulations 2013 is "in press"; it is hoped to publish/publicise this RP/NM-specific guidance on this topic in the next Newsletter

Purchasing of radiopharmaceuticals outside of Radiopharmacy control, and UKRG Guidance on the Safe Drawing up of radiopharmaceuticals

The UKRG *Guidance on the safe drawing up of Radiopharmaceuticals* and the purchase of radiopharmaceuticals refer to the need for a documented agreement between Radiology, Nuclear Medicine and Medical Physics departments and the Trust's Chief Pharmacist. This agreement should describe the responsibilities for delegating the purchase of radiopharmaceuticals, as well as a requirement to discuss with the Chief Pharmacist any purchase of unlicensed materials. An "agreement template" is being prepared by UKRG and will be included in a future issue of the Newsletter, and made available on the UKRG website.

In addition to the template agreement, UKRG is developing an audit proforma for users to test their compliance with the Guidelines. Publication of the audit proforma will be announced in a future issue of the Newsletter; it will be available on the UKRG website along with the Guidelines. [*Editor's note: the Guidelines are already on the website at this URL:* http://www.bnms.org.uk/ukrg/guidance-notes/]

BNMS RADIOPHARMACY PRIZE 2013

UKRG is pleased to announce that the Radiopharmacy Prize at this year's BNMS Annual Meeting, sponsored by IBA Molecular, was awarded to Beth Mills of Nottingham University Hospitals for her presentation entitled: *Towards more - specific imaging of bacterial infection using a FDG derivative.*

Congratulations Beth!

BNMS ANNUAL MEETING 2014 HARROGATE

Readers are encouraged to submit papers for presentation at the Radiopharmacy session at next year's BNMS Annual Meeting which will be held in Harrogate. UKRG will also consider inviting speakers to present on specific topics; if there are topics you would like to see addressed please send details to Jilly Croasdale (j.croasdale@nhs.net), or to the Editor (bob.ardley@nth.nhs.uk)

TPD PORTAL

Hopefully readers are aware of the Pharmacy Technical Professional Development (TPD) Portal, the home of professional development for NHS staff specialising in the technical disciplines of pharmacy. If not, you are encouraged to visit the website (www.tpdportal.org.uk) and register for access (with an NHS e-mail address only). The site has been developed to assist you to progress in your chosen career path within technical services, whatever your background, current level of attainment, or grade. Using this site will help you to analyse your current level of competence, consider your aspirations, focus on your development needs and evidence your achievements along the way.

So far the Portal has concentrated on "traditional pharmacy" technical services. However, recently UKRG has commenced work on a set of cluster-activities and tasks covering radiopharmacy which, when complete, will make the Portal even more use to those practicing radiopharmaceutical science at whatever level. Part of the programme for the UKRG Annual Workshop in Bournville in January 2014 will be devoted to the TPD Portal, so register for the Workshop and see what the Portal can do for you.

REVISION TO EU GMP

Change control and validation requirements will be updated with the forthcoming revision to Annex 15, the consultation on this having closed at the end of February. The outline of the proposed changes is available on the EMA website.

To keep up-to-date with changes in EU GMP readers are advised to bookmark this URL: http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm

REGULATORY ISSUES

Recent MHRA inspections

During 2013-Q2 nine radiopharmacies had received a GMP Inspections. The following summary of the findings was provided by Malcolm Olver, Senior GMP Inspector.

In some instances Investigations were found to be inadequate, for the following reasons:
Investigations had:

- not been carried out in a timely manner;
- had been led by non-radiopharmacy staff;
- had followed a procedure which was not part of the Quality System (QS),
- had involved staff who were not appropriately knowledgeable about Radiopharmacy,
- often resulted in long timescales for CAPA, and
- resulted in recommendations which had not been communicated promptly to the staff responsible for acting on them;
- failed to find the root cause which was a shortage of staff and sickness (the capacity plan was not considered in the investigation).
- often lacked details in the written records;
- shown a lack of urgency in dealing with Bacillus contamination in the Grade A environment.

Malcolm comments: *The value of good investigations and the trending of results in a meaningful manner cannot be overemphasized in providing assurance of asepsis in the handling of sterile products. Picking up trends and recognising that a problem has recurred are vital in dealing with problems. Recurrence means that the root cause has not been identified as the preventative action has failed.*

Quality Systems at some sites were lacking some key elements:

- Risk management including capacity planning;
- Validation procedures, including revalidation policy;
- Little or no change control, (a lack of any change control process, or a lack of sufficient detail and alerting to related systems such as: SOPs, training, and calibration routines that need to be addressed as a result of the change.);
- No TSE process to check regularly for compliance;
- No supplier approval and review process. (deficiencies noted at several sites)

Training deficiencies:

- No risk management training for senior staff. (2 inspections with these findings); *vital in addressing the quality of investigations;*
- Training of operators: lack of a training assessment processes. What to do if an operator fails a periodic validation test?;
- Lack of reviews of training. No consideration of the adequacy of training in operator error investigations as a remedial action.

Equipment deficiencies:

- Isolator leak test results (pass/fail) did not tie up with the numbers recorded. The limits on the record sheet had been exceeded but no comment had been made when the unit indicated a pass. (Amercare unit).
- Isolators in poor condition – Opaque viewing panels; sealant cracking up or rough.
- SLAs/TAs with building and equipment maintenance and servicing providers were inadequate – *make sure these are up to date and that reports are handed over promptly for review after work is completed. Check the results are in specification! Also have a process to pick up on any recommendations made in the service report. (6 inspections)*

Facility deficiencies:

- One site was given a "Major" for its inadequate facility due to poor finishes, layout, and maintenance. Lack of any air flow mapping to detect dead spots.
- One site was given a "Major" for a poor changing room and a prep room open to the corridor with no space to spray and wipe. (This was a repeat deficiency, not corrected since the previous inspection)
- Another site had poor changing facilities (inadequate space, no mirror, no hand gel, poor SOP) and control of gowning for entry to Grade D work room.

Environmental monitoring deficiencies:

- There was no evidence that the incubators used had been temperature mapped, are monitored and alarmed, and the temperature probes are calibrated. (2 inspections with this finding.)
- High growth rates for settle plates not adequately investigated. (Above 10% failures)
- Numerous examples of poor investigations or failures to investigate excursions from the normal results of personnel and environmental monitoring, and failing to consider this situation as part of the release process.

Comment:
Is data available to support the use of contact plates and session plates when "Klericide" disinfectants are used? The question is about the possible inhibitory effect of the spray which should be addressed by use of an inactivation agent in the media if there is the possibility of the spray or its residue on the media.

In summary, Malcolm Olver comments, ***the recent changes to Chapter 1 have underlined the need for good investigations into non-conformances. A reading of the revised chapter is thoroughly recommended!***

FUNDING APPROVED FOR NEW REACTOR AT PETTEN

The European Commission has concluded that a loan of €80 million to be granted by the Dutch authorities to support the construction of a new multipurpose nuclear reactor in Petten (region of Noord-Holland) is in line with EU state aid rules. The Commission found, in particular, that the aid will contribute to the security of supply of medical radioisotopes for the benefit of European patients and to other objectives of common interest without unduly distorting competition in the internal market.

Full details are in the EC press briefing which can be found at this URL: http://europa.eu/rapid/press-release_IP-13-700_en.htm

INDUSTRY NEWS

UKRG Disclaimer: Information in this section is proffered by UKRG Industry colleagues. Inclusion in the Newsletter does not imply endorsement of any particular product by the UKRG.

Alliance Medical Ltd (AML) increases UK market share of F18-FDG supply.

In August Alliance Medical Ltd (AML) took full ownership of Erigal by buying out the 50% stake owned by M2i Holdings (Eire). On 17th September AML then acquired the IBA Molecular's UK F-18-FDG production facility. Details are in the AML press releases at these URLs:
http://www.alliancemedical.co.uk/AMMIL and
http://www.alliancemedical.co.uk/ibaaquisition

"Synchrom" combined PET synthesis/ QC unit, and "GAIA" Gallium synthesis module

Raytest UK is now offering the Synchrom, a flexible automated unit combining both synthesis and HPLC in one system. This compact, dual reactor, system can be programmed by the user for a wide variety of PET compounds, including FLT, FET, FEC and nucleophilic F-DOPA.

Raytest UK also markets the GAIA Gallium synthesis module, as well as a range of QC instruments.

For further information contact Andy Holley, *Raytest UK, Sales Consultant:* tel: 01344 762022, mob: 07912 479150, e-mail andy@raytestuk.co.uk , website www.raytestuk.co.uk

New Products / Withdrawal of Products / Supply Issues

UKRG Disclaimer: Information in this section is proffered by UKRG Industry colleagues. Inclusion in the Newsletter does not imply endorsement of any particular product by the UKRG.

DraxImage Medronate (MDP)

Diagnostic Imaging Ltd. (DIL), the UK exclusive distributor for Jubilant DraxImage, is pleased to announce that the UK licensed DraxImage MDP kit is now available [*Editor's note: UKRG understands that DIL will be able to fulfil orders from Mon 7th Oct 2013*]. The kits are in 5 vial packs. Key features are:

- up to 18.5 GBq of Tc99m-pertechnetate may be added;
- a maximum reconstitution volume of 10ml; and
- a 12 hour shelf life at room temperature after reconstitution.

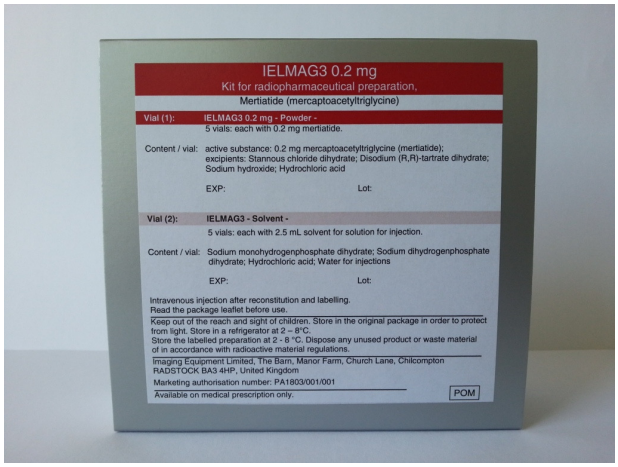
Please contact Mike Barker at Diagnostic Imaging Ltd for more information: tel 0845 226 0520, or mailto:mikebarker@diagimaging.com

IELMAG3 0.2 mg Launches in UK

Imaging Equipment Limited has launched a new non-boil MAG3 cold kit – "IELMAG3" - to the UK and Ireland radiopharmaceutical market [*Editor's note: this is the Rotop MAG3 kit*]. The IELMAG3 0.2mg kit contains two vials; vial 1 is a freeze dried MAG3 (0.2mg mertiatide) and vial 2 is a phosphate buffer. The kit is prepared by the addition of up to 2.5 GBq of Tc99m-pertechnetate to IELMAG3 0.2mg vial 1, with an incubation time of 15 minutes, and then through the addition of the phosphate buffer, the reaction is stabilised. IELMAG3 0.2mg has a post reconstitution shelf life of 6 hours and can be diluted up to 10mls with 0.9% saline. The IELMAG 0.2mg has the same clinical equivalence as traditional MAG3 kits, but with several advantages to the UK hospital Radiopharmacy. It is a non-boil product which makes it easy and safe to prepare, has a longer shelf life than the current MAG3, and it is possible to add a higher activity to the IELMAG3 kit meaning that a greater number of patient doses can be achieved. A 6 hour reconstitution enables imaging to take place in both morning and early afternoon sessions. Following reconstitution with Tc99m-pertechnetate, IELMAG3

is used for the valuation of nephrological and urological disorders, in particular for the study of function, morphology and perfusion of the kidneys and the characterisation of urinary outflow.

For more details about this product, please contact Imaging Equipment Limited at pharma@imagingequipment.co.uk



XOFIGO Ra223-Chloride

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended that Bayer Pharma AG be granted a marketing authorisation (MA) for the medicinal product Xofigo, 1000 kBq/mL, solution for injection, intended for the treatment of adults with castration-resistant prostate cancer, who have symptomatic bone metastases and have no known visceral metastases. Known in clinical trials as Alpharadin, the licensed product was renamed Xofigo upon recent launch in the USA. Phase III studies were terminated early due to a significant survival benefit being demonstrated, something which is not seen with Sr-89-Chloride (Metastron). Xofigo is given once a month for 6 months.

Once the European MA has been granted copies of the summary of product characteristics (SmPC) should be available from Bayer and on the European public assessment report (EPAR) website

Hetastarch – Hydroxyethyl-Starch (HES)

Readers may be aware that in June this year the EMA recommended suspending the marketing authorisations for infusion solutions containing hydroxyethyl-starch ("Hetastarch") on the basis that the benefits of using such infusions no longer outweigh the risks. One adverse consequence of this ruling for Radiopharmacy is the impact it will have on cell labelling procedures, specifically when used for red cell sedimentation. UKRG is pleased to note that the EANM has written to the EMA to ask [the EMA] to state precisely that the above marketing restriction is only valid for intravenous infusions of hydroxyethyl-starch and does not apply to in vitro preparation procedure of radiolabelled white-blood-cells and platelets. Confirmation from the EMA is awaited.

Other new products that UKRG is aware of include:

Lymphoseek (tilmanocept) kit for Tc-99m labelling (distributor to be announced) [*Editor's note: watch out for an announcement in a future Newsletter*]. This is the first product specifically licensed as a sentinel node imaging and localisation agent for SLNB. It is non-particulate in nature, being a DTPA mannosyl dextran derivative and requires strict conditions for labelling under the terms of its SPC.

EdiCIS (ethylene dicysteine, EC) kit for Tc-99m labelling (IBA Molecular UK). This product is a non-boil kit but needs a buffering step. Tc-99m EC is excreted both by glomerular filtration and tubular secretion in a manner closer to Hippuran than does MAG3 and consequently has a different extraction factor value to MAG3. EdiCIS has been in use in Hungary since 1992 and France since 2010.

For further information contact Mike Ward at IBA Molecular UK Ltd, tel: 01483 301638, e-mail mike.ward@ibamolecular.com .

Amyvid (F-18 florbetapir) became licensed and available from 4th June on the UK market. Manufactured by Siemens at the Nottingham PetNet site, it is licensed as a plaque density imaging agent for the clinical evaluation of Alzheimer's Disease and other cognitive impairment. For further information contact Gill Mason (gill.mason@siemens.com)

SPC Updates

Whilst notification to customers of changes to SPC is the responsibility of suppliers UKRG welcomes the opportunity to disseminate news of such updates.

GE Healthcare has issued (August 2013) an updated SPC for "Metastron" Strontium (Sr89) Chloride. The changes concerns section 4.4. Special warnings: where the following has been added: *"A calcium-like flushing sensation has been observed in patients following a rapid (less than 30 second injection) administration"*.

Copies of the revised SPC can be downloaded from the GE Customer Portal at this URL:
http://libraries.ge.com/download?fileid=422150469101&entity_id=29178525101&sid=101

Other recent SPC updates since April 2013 include for the following: Cr-51-EDTA; I-123-Ioflupane (DaTSCAN); Rapiscan (Regadenason); and Se-75-HCAT capsules.

The full list of GE Healthcare SPCs is available for the Customer Portal at this URL:
https://libraries.ge.com/foldersIndex.do?entity_id=29178525101&sid=101&sf=1#29178525101

RADIOPHARMACY DESIGN

A two-day symposium on Radiopharmacy design is to be held at St Bartholomew's Hospital, London, on 24th-25th October 2013. If any Newsletter reader is interested in this meeting and has not already received an invitation to attend, details can be obtained from Neil Hartman at this e-mail address neil.hartman@bartshealth.nhs.uk

POSTGRADUATE COURSE IN RADIOPHARMACY - 2013

The annual Postgraduate Course in Radio-pharmacy will be held Tuesday 10th to Friday 13th December 2013 at St Thomas Hospital, Waterloo, London. Further details and on-line registration can be found at:
https://www.kcl.ac.uk/prospectus/shortcourses/details/name/postgraduate-course-in-radiopharmacy-2013/keyword/medicine

For further information please contact: teachingadmin-imaging@kcl.ac.uk

UPCOMING MEETINGS

2013

15th International Symposium on Radionuclides in Nephrourology
Date: 15–17 October, Varese, Italy
Website: www.iscorn2013.org

EANM'13 Annual Congress of the European Association of Nuclear Medicine
19-23 October, Lyon, France
Website: www.eanm.org

9th National Cancer Research Institute Conference
3–6 November, Liverpool, UK
Website: www.ncri.org.uk/ncriconference

ICRT 2013: WARMTH 8th International Conference on Radiopharmaceutical Therapy
17–21 November, Manila, The Philippines
Website: www.icrt-2013.warmolth.org

Imaging Infections and Inflammation
12–14 December, Rome, Italy
Contact: alberto.signore@uniroma1.it

2014

UKRG Annual Workshop: Continuing Professional Development in Radiopharmacy
Date: 17th January 2014, Bournville, UK
Website: www.ukrg.org

ESRR'14 European Symposium on Radiopharmacy and Radiopharmaceuticals
24-27 April, Pamplona, Spain
http://esrr14.eanm.org

BNMS Spring Meeting
11–14 May 2014, Harrogate, UK
Website: www.bnms.org.uk

11th Congress World Federation of Nuclear Medicine and Biology (WFNMB)
27-31 Aug, Mexico
www.wfnmb.org

From the Editor

My thanks to all who contributed items for inclusion in this issue of the Newsletter.

The next meeting of the UKRG Committee will take place at Guy's Hospital, London, on 8th October 2013; the one after that will be at Bournville on 15th-16th January 2014 prior to the Annual UKRG Workshop.

If readers have any issues they wish to be discussed please raise them with your regional rep on the Committee. Alternatively, comments on the Newsletter content or on any radiopharmacy issue can be sent direct to the Editor at the address below.

www.ukrg.org.uk	*Editor:* Bob Ardley Please note my new address Regional Medical Physics Department University Hospital of Hartlepool Holdforth Road, Hartlepool, UK, TS24 9AH Phone: 01429-522681; Fax: 01429-860052 E-mail: bob.ardley@nth.nhs.uk
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The Royal Liverpool and Broadgreen University Hospitals NHS Trust

Radiopharmacy Department

U.K. Radiopharmacy Group

Direct line: 0151-706-4521
Direct fax: 0151-706-4522
E-mail: paul.maltby@rlbuht.nhs.uk

1 October 2013

Dear Colleague

UK Radiopharmacy Group Workshop January 17th 2014
Beeches Management Centre, Bournville, Birmingham

Please find attached the booking form and provisional programme for the forthcoming meeting. As usual, places are limited; thus applications will be dealt with on first come first served basis. Please note that acceptance of registration will only be confirmed on receipt of the course fees in full prior to the course commencing. Payment will be *by either personal or hospital cheque or BACS only.* **No invoices will be issued against raised order numbers, (cheques with order only)**. For those wishing to pay by BACS, details are outlined on the form below. Receipts will be issued within 2 weeks of payment being made. As in previous years, overnight accommodation will be available at The Beeches for the night of 16th January.

I look forward to seeing you in Bournville.

Yours sincerely,

Paul Maltby
Chief Radiopharmacist

UK RADIOPHARMACY GROUP WORKSHOP 2014

Bournville 17th January 2014

Continuing Professional Development in Radiopharmacy

Beeches Management Centre Birmingham

BOOKING FORM

-

Name
BLOCK CAPITALS PLEASE

Organisation

Address

Telephone number **Fax**

Email:

Please book a place for me as follows:

Course fee (includes lunch and refreshments)	£100
Bed and Breakfast accommodation for the evening of 16th January (delete as appropriate)	£75
Bed and Breakfast accommodation for the evening of 15th January (delete as appropriate)	£75
TOTAL	**£**

(Cheques made payable to UK Radiopharmacy Group)

Hospitals wishing to pay by BACS transfer, the details are:

Bank:	National Westminster	Sort Code:	60-02-35
Address:	Birmingham City Office 1 St Phillips Place, Birmingham B3 2PT	Account Name: Account Number:	UK Radiopharmacy Group 30684749

Conditions of booking:
Completed Booking Forms with details of accommodation requirements, together with a cheque (or confirmation of BACS) for the full amount due, should reach the Radiopharmacy Department no later than 31st December 2013. Those wishing to enrol later than the time specified should contact the organiser in the first instance. In the event of cancellation, if WRITTEN NOTICE reaches the organiser:

- **up to 28 days before the Workshop, 25% of the total fees payable will be charged**
- **less than 28 days before the Workshop 100% of the total fees payable will be charged**

(Please note substitutes will be accepted upon notification)

This booking form should be returned with appropriate fee to: Mr. Paul Maltby, Radiopharmacy Department, Royal Liverpool and Broadgreen University Hospital, Prescot St, Liverpool L7 8XP
In the event of any query please phone 0151 706 4521

U.K. Radiopharmacy Group

Radiopharmacy Workshop
Bournville 17th January 2014

Continuing Professional Development in Radiopharmacy

Provisional Programme

Morning	
Registration and Coffee 09.00 – 09. 15	
New Radioactive Medicinal Products in Nuclear Medicine	
09.15 – 09.35	IELMAG3
	Jeevan Virk - IEL
09.35 – 09.55	Lymphoseek
	Navidea Speaker
09.55 – 10.15	Amyvid
	Matt Green Lilly
Coffee and exhibition 10.20 – 11.10	
11.10 – 11.30	Nanosized colloid (Sentiscint)
	MediRadiopharma speaker
11.30 – 11.50	Edicis
	IBA Speaker
11.50 – 12.10	Xofigo
	Bayer speaker
CPD - Development of the Technical Professional Development (TPD) Portal for Radiopharmacy	
11.50 – 12.10	Background to the TPD
	Rachel Dixon
12.10 – 12.30	Introduction to the Workshop
	UKRG Speaker
Lunch & Exhibition 12.30 – 14.15	
Afternoon Syndicate work	
Introduction	
14.15 – 14.20	Syndicate Group Assignment
	Paul Maltby
14.20 – 15.30 Workshops - Parallel Sessions “”	
• Group1	
• Group 2	
• Group 3	
• Group 4	
Reporting back from syndicates 15.30 – 1600	
Summing up 16.00 – 16.10	
Depart	