**Aim:** In recent years several radiofluorinated ligands targeting the prostate-specific membrane antigen (PSMA) have been reported [1,2]. Our aim was to optimize the two-step synthesis procedure of $^{18}$F-PSMA-1007 [3] towards a simplified and automated single-step synthesis, thereby fulfilling GMP compliance. **Materials and Methods:** A labelling precursor for direct nucleophilic substitution using trimethylammonium as leaving group has been developed. After azeotropic drying of [$^{18}$F]fluoride using tetrabutylammonium hydrogen carbonate solution as base, the fully automated radiosynthesis of $^{18}$F-PSMA-1007 has been conducted on several commercially available automated radiosynthesizers (GE TRACERlab FX FN, MX and FASTLab, ORA Neptis Plug and RS, IBA Synthera) using 1.5 to 3.0 mg of precursor in DMSO for 10 minutes at 85 °C. The crude reaction mixture was taken up in water containing sodium ascorbate and trapped on pre-conditioned sequenced SPE cartridges (Chromafix PS-H+ and Chromafix C18ec, Macherey-Nagel). After rinsing with 5% EtOH solution, the purified product was eluted from the cartridges with 30% EtOH solution and diluted with 0.9% NaCl solution containing sodium ascorbate. After sterile filtration, quality control for $^{18}$F-PSMA-1007 was performed according to specifications set in compliance with current pharmacopoeias. **Results:** $^{18}$F-PSMA-1007 could be obtained in radiochemical yields ranging from 30-50% and radiochemical purities > 90 % in a total synthesis time of < 60 min in dependence of the type of radiosynthesizer (GE TRACERlab FX FN, MX and FASTLab, ORA Neptis Plug and RS, IBA Synthera ) synthesis module used. No radiolysis of the product has been observed up to 8 hours after final batch formulation (40 GBq in 20 mL saline solution). **Conclusion:** A GMP-compliant radiosynthesis and quality control of $^{18}$F-PSMA-1007 using direct radiofluorination including a simplified purification procedure have been established on a wide range of commercially available radiosynthesizers (GE TRACERlab FX FN, MX and FASTLab, ORA Neptis Plug and RS, IBA Synthera). The product is obtained in good radiochemical yields with satisfying batch productions covering the daily clinical demand in a university hospital. Radiopharmaceutical quality will allow the initiation of prospective clinical trials. **References:** [1] Rowe SP ***et al.***. Prostate Cancer Prostatic Dis. 2016 19(3):223-30. [2] Giesel FL ***et al.***. Eur J Nucl Med Mol Imaging. 2017 44(4):678-688. [3] Cardinale J ***et al.***. J Nucl Med. 2017 58(3):425-431.

## OP-441

### Automated Synthesis of Pt-195m Cisplatin for GMP Production

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**Purpose/Introduction:** Imaging of the ***in vivo*** biodistribution of Platinum-based Cisplatin may allow to predict treatment outcome of chemo(radio)therapy in a personalized approach. We have shown the feasibility of Pt-195m SPECT imaging in mice[1], and we have adopted a known procedure[2] for the manual synthesis of Pt-195m Cisplatin for its preclinical use. To reduce synthesis time and to simplify the multistep process of the making of Pt-195m Cisplatin, we have now developed a fully automated synthesis module, ready for GMP production. **Subjects & Methods:** First, chemical resistance of materials to ***aqua regia*** and concentrated hydrochloric acid was tested in a proof of concept study, and a method for the automated separation of precipitates from solution using filters was developed. Subsequently, different reaction vials, reagent vials, valves, tubing and filters were tested, and methods for dispensing, evaporation of solvents, and transfer of solutions using nitrogen gas flow were developed. A semi-automated prototype was built and tested for its performance of radioactive syntheses of Cisplatin, after which the fully automated module was designed and built. **Results:** Tests to synthesize Pt-195m Cisplatin were successfully performed with the semi-automated prototype, showing a reduction in synthesis time from 2 days to 1 day. Pt-195m Cisplatin was obtained in an overall yield of 48 %, and in high radionuclide and radiochemical purity. The automated module contains a distinguished pharmaceutical part, including a sterile section to produce sterile Pt-195m Cisplatin. All parts in contact with solvents, reagents, and the radioactive reaction mixture or the product, are fully disposable. **Discussion/Conclusion:** A fully automated synthesis module for the GMP production of Pt-195m Cisplatin has been developed. A human pilot study is under preparation. The module will also be used for the development of other Platinum-195m compounds. Since Platinum-195m is a very strong Auger electron emitter, we are currently pursuing development of Pt195m with high specific activity for therapeutic applications as well. 1: Aalbersberg, E.A., de Wit-van der Veen, B.J., Zwaagstra, O., Codée-van der Schilden, K., Vegt, E., Vogel, W.V. Preclinical imaging characteristics and quantification of Platinum-195m SPECT, Eur. J. Nucl. Med. Mol. Imaging (2017). DOI:10.1007/s00259-017-3643-2 2: Hoeschele, J.D., Butler, T.A., Roberts, J.A., Guyer, C.E. Analysis and refinement of the microscale synthesis of the $^{195m}$Pt-labeled antitumor drug, ***cis***-Dichlorodiammineplatinum(II), ***cis***-DDP. Radiochimica Acta (1982), 31, 27-36.

## OP-442

### Automatic synthesis of a PSMA ligand with Al$^{18}$F

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**Introduction:** PSMA-targeting positron emission tomography (PET) probes have become available for prostate cancer imaging. The $^{68}$Ga-labeled PSMA ligands have been extensively studied. However, $^{68}$Ga labeled compounds are produced with generators providing limited activity per synthesis. In contrast, $^{18}$F-labelled tracers allow higher doses increasing the number of examined patients. In addition, late images can be acquired in the case of uptake in lymph nodes, to discard inflammation. It is important to transfer the manual synthesis to an automatic module, producing a batch of the radiopharmaceutical with high activity in a safe and effective way. The aim of this work was to optimize the labeling of Al$^{18}$F-[GLU-UREA-LYS(AHX)-HBED-CC] in a Tracerlab-FXFN (GE) platform. **Materials and Methods:** All reagents were of analytical grade. PSMA was purchased from ABX (PSMA-11). The $^{18}$F was produced in a PET-Trace cyclotron

(16,4 MeV) and transferred directly to the Tracerlab-$FX_{FN}$ (GE). The $^{18}F$ was purified with a QMA cartridge (Waters) and then eluted with 500 µL acetate buffer pH=4.5 (0.5M) from vial 1 to reactor. The first step in the synthesis was the formation of the $Al^{18}F$. For this purpose, the reactor contained 4,5µL of 0.01M $AlCl_3$ in acetate buffer pH=4.0 (5 min at 25°C). A solution containing 60 µg of PSMA-11, 500 µL of EtOH and 700 µL of 0.5M sodium acetate was then added from vial 4. The reaction took place during 10 minutes at 50°C. The product was purified by HPLC using a $C_{18}$ column (250/10 M&N) with two mobile phases (8mL/min): buffer phosphate 10 mM, pH=6.8: EtOH [A: (98:2) for 15 min. and change to B:(92:8)]. The collected peak was transferred by sterilizing filtration to the final vial. Quality control was performed via radio HPLC and GC. **Results:** The labeling up to the reactor corroborates the formation of the complex $Al^{18}F$-PSMA. After purification by HPLC, the radiopharmaceutical was achieved with a radiochemical purity higher than 90%. The quality control of the final product fulfilled all the requirements in agreement with USP, such as radiochemical purity (greater than 90%) and residual solvents. $Al^{18}F$-PSMA was obtained with a yield of 15±2 % (n=3), not decay corrected (NCD) starting off from 500 to 1500 mCi the $^{18}F$ and with a radiochemical purity of 95 ± 3 %. **Conclusion:** The proposed method allowed the production of $Al^{18}F$-PSMA with suitable radiochemical purity in a commercial platform. High activities were achieved, with a simple and robust methodology appropriate for clinical purposes.

**1106** **Tuesday, October 24, 2017, 08:00 - 09:30, Hall F1**

## Pitfalls & Artefacts 5 (Interactive) - Oncology: Pitfalls and Artefacts of PET in Neuroendocrine Tumours

### OP-443

**18F-fluorodopa**

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### OP-444

**Somatostatin Receptor PET/CT in Gastro-Entero-Pancreatic (GEP) NEN**

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### OP-445

**Somatostatin Receptor PET in Other NET**

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**1107** **Tuesday, October 24, 2017, 08:00 - 09:30, Hall F2**

## Clinical Oncology: Cured or Not Cured?

### OP-446

**Accuracy of F-18-FDG-PET/CT in monitoring tumour response after neoadjuvant chemoradiotherapy (nCRT) in patients with locoregional oesophageal cancer**

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**Introduction:** Neoadjuvant chemoradiotherapy (nCRT) with "CROSS" (NEJM 2012) is effective for downstaging oesophageal tumours. To safely postpone surgery, reliable clinical response evaluations (CREs) should be used to rule out residual locoregional disease without distant metastases. A multicentre feasibility study is underway (preSANO trial, NL41732.078.13) including endoscopy, (deep) biopsies, ultrasound and FDG-PET/CT with planned surgery 12 weeks after nCRT. This preliminary analysis focuses on FDG-PET/CT to predict residual tumour (substantial: >10%=TRG3-4 vs minimal: ≤10% vital cells=TRG1-2,) or metastases after nCRT. **Subjects & Methods:** FDG-PET/CT at baseline and CRE was performed according to EANM guidelines 1.0 (2.3MBq/kg F-18-FDG; scanning 60±5min.). Visual: presence of residual tumour and/or metastases; SUV and SUV/lean body mass (SUL); compared with pathology (resection specimen: golden standard). **Results:** 78 of 205 patients did not proceed to FDG-PET/CT follow-up at 12 weeks after nCRT (CRE2), including 4 with FDG-negative baseline scans and 4 with FDG-positive metastases at 6 weeks (CRE1). In 127 patients at CRE2, FDG-PET/CT was positive in 87. In 5/87, data on histology were still incomplete. 25/87 had no resection (7 postponed, 14 metastases on FDG-PET/CT, 1 died, 3 metastases peroperatively). 33/87 patients had TRG3-4 tumour; SUL-max 4.27±1.63 and SUL-max-ratio tumour/oesophagus (SULR) 2.09±0.77. 12/87 patients had (TRG2) tumour; SUL-max 3.48±0.79 and SULR 1.66±0.33. Of all 27 patients with TRG1, FDG-PET/CT was false positive in 12/27 (44%); SUL-max 3.67±1.14, SULR 1.83±0.57. In all 80 patients with TRG2-3-4-metastases, FDG-PET/CT was true positive in 66/80 (83%). In 40/127 patients at CRE2, FDG-PET/CT was negative. In 7/40 surgery was postponed. 25/40 patients had TRG1-2 tumour; SUL-max 2.28±0.65, SULR 1.22±0.21. Of all 41 patients with TRG3-4, 8/41 were missed on FDG-PET/CT (20% false negative); SUL-max 2.18±0.26, SULR 1.38±0.13. However, in 5/8 surgery was >4weeks after PET/CT. Still, in 7/8 patients radical resection was achieved. Of all patients with postponed surgery, 12 had ≥1 additional FDG-PET/CT during follow-up (25-49.7 weeks). In 6/12, FDG-signal remained low or decreased (ΔSUL-max -0.34±0.48); 6/12 had increased FDG-signal (ΔSUL-max 0.98±0.47). 4/12 had surgery; 3/4 had increased FDG-signal and TRG3-4 tumour at surgery; 1/4 patients had decreased FDG-signal and no tumour (TRG1). All four patients had radical resections. **Conclusion:** These preliminary results indicate that FDG-PET/CT is valuable in follow-up after nCRT. Positive FDG-PET/CT after nCRT predicts residual tumour in 83% of patients. However, visual and quantitative FDG-PET/CT alone is not sufficiently accurate. Therefore, final results of FDG-PET/CT combined with endoscopic ultrasound and (deep) biopsy results should be awaited.