



International Isotope Society UK Group

30<sup>th</sup> Annual Symposium

The Synthesis and Applications of  
Isotopically Labelled Compounds

Friday, 15<sup>th</sup> November 2024

The Møller Institute, Cambridge

<https://www.iis-uk.org>

# Sponsors

The organising committee would like to thank the following companies for their generous sponsorship:



# Welcome & Acknowledgements

On behalf of the organising committee, it is my pleasure to welcome you to the 30<sup>th</sup> annual symposium of the International Isotope Society UK Group on the synthesis and applications of isotopically labelled compounds held, once again, at The Møller Institute in Cambridge.

Professor Jason Holland from the University of Zurich, Switzerland will open the meeting with a talk titled "*New tactics in radiotracer design (radiometals)*." Our afternoon session will be opened by Dr Katherine Wheelhouse from GlaxoSmithKline with a talk titled "*Adventures in pharmaceutical catalysis*."

Today's programme will also cover a multitude of topics including, radical chemistry, (bio)catalysis, imaging and labelling with deuterium, tritium, carbon-14 and fluorine-18. I hope you'll find plenty of topics of interest.

I would like to thank all our speakers and those presenting posters for joining us today and taking the time to share their work. I'd also like to thank our sponsors and exhibitors for their generous support both this year and in years past. My thanks also go to our session chairs and to the staff of The Møller Institute for helping us to stage this event. This meeting would not have been possible without the dedication and enthusiasm of the organising committee — my thanks go to all involved.

Lastly, I have to thank you all for attending and helping to make this event so successful. I hope you have a very enjoyable day.

Chris Winfield.  
Chair, IIS UK Group.

## Organising Committee

Dr Ryan Bragg	ryan.bragg@astrazeneca.com
Dr Alan Jeuken	alan.jeuken@quotientsciences.com
Professor Sofia Pascu	sp350@bath.ac.uk
Dr Daniela Roman (Treasurer)	daniela.x.roman@gsk.com
Dr Graham Smith	gs739@medschl.cam.ac.uk
Dr Andrew Watson	andrew.watson@pharmaron-uk.com
Professor Chris Willis	chris.willis@bristol.ac.uk
Dr Chris Winfield (Chairman)	chris.winfield@selcia.com

# Scientific Programme

- 8:30 am Registration, morning coffee & manufacturers exhibition.  
9:00 am Welcome: Dr Chris Winfield (Eurofins Selcia, Chair of the IIS UK Group).

## Morning Session 1

Chair: Professor Chris Willis (University of Bristol, UK).

- 9:05 am **Professor Jason Holland** (University of Zurich, Switzerland),  
*New tactics in radiotracer design (radiometals).*
- 9:55 am **Dr Siôn Edwards** (Pharmaron, UK),  
*Tritium labelling of oligonucleotides.*
- 10:20 am **Dr Jack Rowbotham** (University of Manchester, UK),  
*Integrating biocatalysis into the synthesis of deuterated drugs and other valuable biomolecules.*
- 10:45 am Manufacturers' exhibition, poster session, tea & coffee.

## Morning Session 2

Chair: Dr Geoff Badman (GlaxoSmithKline, UK).

- 11:20 am **Professor Rebecca Melen** (Cardiff University, UK),  
*Single or double? A radical approach to frustrated Lewis pairs.*
- 11:45 am **Dr David Lindsay** (University of Strathclyde, UK),  
*New catalytic approaches for rapid access to isotopically-labelled architectures of biological importance.*
- 12:10 pm Buffet lunch, manufacturers' exhibition & poster session.

## Afternoon Session 1

Chair: Dr Graham Smith (University of Cambridge, UK).

- 1:25 pm **Dr Katherine Wheelhouse** (GlaxoSmithKline, UK),  
*Adventures in pharmaceutical catalysis.*
- 2:15 pm **Dr Philip Miller** (Imperial College London, UK),  
*Droplet-based F-18 radiolabelling reactions.*
- 2:40 pm Manufacturers' exhibition, poster session, tea & coffee.

## Afternoon Session 2

Chair: Dr Andrew Watson (Pharmaron, UK).

- 3:15 pm **Dr Cinzia Imberti** (Kings College London, UK),  
*Metallodrugs in the hot seat: accelerating preclinical development with radionuclide imaging.*
- 3:40 pm **Dr Sean Kitson** (Almac Sciences, UK),  
*Application of nitrilase in [<sup>14</sup>C]SHP-141 synthesis: advancing Remetinostat, an HDAC inhibitor.*
- 4:05 pm Concluding Remarks: Chris Winfield (Eurofins Selcia, Chair of the IIS UK Group).

## Presentation Abstracts

# New Tactics In The Design Of Radiotheranostics

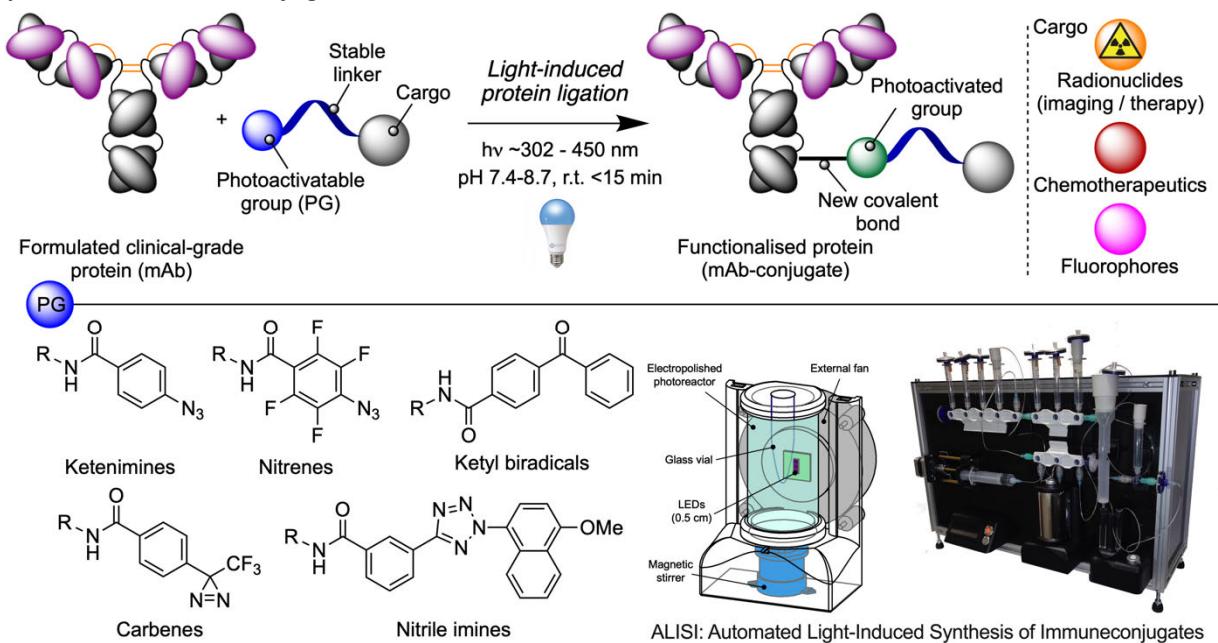
Professor Jason Holland

Department of Chemistry, University of Zürich

Jason.holland@chem.uzh.ch

Radiopharmaceuticals play an increasingly important role in the clinic and are already at the front line of diagnostic medicine for brain disorders, heart disease, and cancer. As the field of Nuclear Medicine moves inextricably toward the use of a growing palette of highly energetic radiotherapeutic nuclides that cause targeted damage to tissue, many of the fundamental concepts of radiopharmaceutical design that have emerged in the last 50 years need revising. In the context of radiotherapy, the assured specificity, affinity, high uptake, and comparative ease of developing new agents against emerging targets make monoclonal antibodies (mAbs) a vital branch of radiopharmaceutical chemistry. Yet current radioimmunoconjugate designs lead to high dosimetry in radiation sensitive background tissues like the liver, kidney, spleen, bone (marrow) and blood pool. This complicates patient management and can lead to adverse side-effects that compromise patient outcome and well-being. This presentation will explore new chemical methods for creating radiolabelled antibodies using alternative methods including photochemically mediated bioconjugation processes (Figure 1), non-covalent supramolecular strategies, and alternative linker technologies to tailoring radiotracer pharmacokinetics at a tissues-specific level and control dosimetry.

**Figure 1.** Photoradiosynthesis of labelled mAbs using light to drive the formation of novel types of bioconjugate bond, and a schematic of novel reaction platform (ALISI) for the automated light-induced synthesis of immunoconjugates.



## Tritium Labelling of Oligonucleotides

Dr. Siôn Edwards  
Pharmaron UK, Cardiff  
sion.edwards@pharmaron-uk.com

Oligonucleotides are single- or double-stranded DNA or RNA molecules typically containing 12-25 nucleobases. They are widely used in molecular biology, and have important applications in the characterisation, tracking, and measurement of nucleic acids. Oligonucleotides are also developing as an important class of biopharmaceuticals with the potential to combat a broad spectrum of genetic and hereditary diseases. Therapeutic oligonucleotides can modulate gene expression or alter the function of a patient's RNA, allowing diseases to be precisely targeted at a molecular level. Oligonucleotides are commonly prepared via solid phase synthesis, allowing for a variety of structural modifications to be installed in each sequence. Some common classes of therapeutic oligonucleotides include antisense oligonucleotides (ASOs), small interfering RNAs (siRNAs), and aptamers, each with structural features that impart distinct mechanisms of action.

The variety in oligonucleotide structure presents plentiful opportunities for radiolabelling. Radioisotopes such as  $^3\text{H}$ ,  $^{14}\text{C}$ ,  $^{32}\text{P}$ , and  $^{35}\text{S}$  can be exchanged for natural abundance isotopes in the sugars, the nucleobases, and/or the phosphate backbone. Tritium in particular is useful for radiolabelling larger molecules due to its relatively high specific activity by comparison with  $^{14}\text{C}$ , and the variety of positions it can be incorporated within the structure. This talk will discuss some background on oligonucleotides, oligonucleotide synthesis, and general strategies for radiolabelling oligonucleotides with  $^{14}\text{C}$  and  $^3\text{H}$ . The talk will then conclude with an outline of the gold-standard  $^3\text{H}$ -labelling service performed at Pharmaron.

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# Integrating Biocatalysis Into The Synthesis Of Deuterated Drugs And Other Valuable Biomolecules

Otun C.,<sup>1</sup> Reeve H. A.,<sup>2</sup> Vincent K. A.,<sup>3</sup> Rowbotham J. S.,<sup>1</sup>

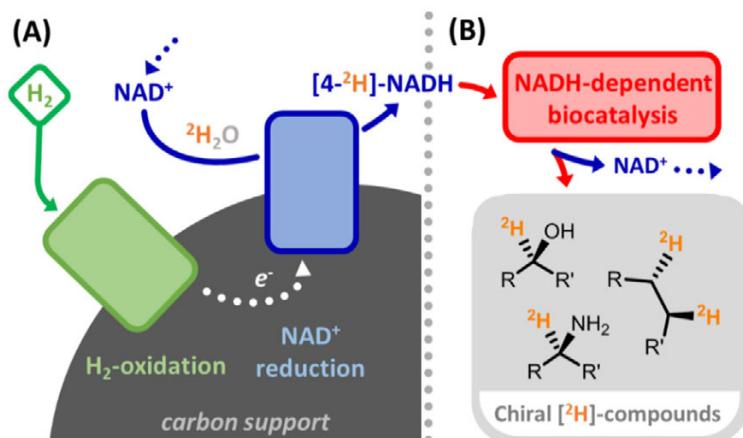
<sup>1</sup>Manchester Institute of Biotechnology, Department of Chemistry, University of Manchester, Manchester, UK.

<sup>2</sup>Department of Chemistry, University of Oxford, Oxford, UK.

<sup>3</sup>HydRegen Ltd., Oxford, UK.

jack.rowbotham@manchester.ac.uk

New challenges in asymmetric catalysis are arising in the field of deuterium labelling, where compounds bearing deuterium (<sup>2</sup>H) atoms at chiral centers are becoming increasingly investigated as potential "heavy drug" candidates.<sup>[1]</sup> Enzymes are well-known to be versatile, tunable, and highly selective catalysts, and they can make a valuable addition to the toolbox of synthetic techniques for asymmetric deuteration. This talk will discuss two key strategies for biocatalytic deuteration: (i) reductive deuteration based on NADH-dependent enzymes, and (ii) enzymatic methods for hydrogen isotope exchange (HIE). As a case study, the talk will explore reductive deuteration based on the *HydRegen* technology, where a clean reductant ( $H_2$ ) can be coupled with a cheap source of <sup>2</sup>H-atoms (<sup>2</sup>H<sub>2</sub>O) in order to generate [4-<sup>2</sup>H]-NADH *in situ* (Figure 1A).<sup>[2,3]</sup> By coupling the [4-<sup>2</sup>H]-NADH-recycling system to an array of C=O, C=N, and C=C bond reductases, it is possible to perform asymmetric deuteration across a range of organic molecules (Figure 1B).<sup>[2-4]</sup> The presentation will explore how these new approaches to biocatalytic deuteration can be utilised in the synthesis of heavy drugs and other valuable isotopically labelled molecules,<sup>[5]</sup> and how they can be adapted for application in continuous flow.<sup>[6]</sup>



**Figure 1. (A)** A catalytic strategy to H<sub>2</sub>-driven *in situ* formation of [4-<sup>2</sup>H]-NADH.  
**(B)** Preparing chiral deuterated compounds from [4-<sup>2</sup>H]-NADH.

## References

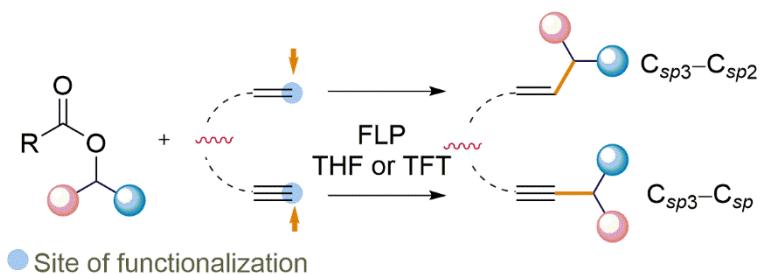
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# Single or Double? A Radical Approach to Frustrated Lewis Pairs

Professor Rebecca Melen

School of Chemistry, Cardiff University, Cardiff

The donor-acceptor ability of frustrated Lewis pairs (FLPs) has led to widespread applications in recent years.<sup>[1]</sup> Recently, it was shown that single electron transfer (SET) from a Lewis base donor to a Lewis acid acceptor can produce a frustrated radical pair (FRP) species. This depends on both the substrate and energy required (photochemical or thermal) to promote an FLP into an FRP.<sup>[2]</sup> In this lecture, we will discuss the C–C<sup>[3,4]</sup> (see Figure) and C–S<sup>[5]</sup> bond forming reactions using FLPs. The nature of these reaction pathways as well as their selectivity has been investigated by extensive electron paramagnetic resonance (EPR) studies, kinetic studies, and density functional theory (DFT) calculations both to elucidate the mechanism of these coupling reactions.



**Figure 1.** Cross-coupling reactions using FLPs.

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# The Development of Iridium Catalysts For C(sp<sup>3</sup>)-H Hydrogen Isotope Exchange

David M. Lindsay,<sup>\*1</sup> Adele E. Queen,<sup>1</sup> Megan Cuthbert,<sup>1</sup> Liam P. Raeside,<sup>1</sup> Andrew McAleer,<sup>1</sup> Lucy Pryde,<sup>1</sup> David Hesk,<sup>2</sup> Sumei Ren,<sup>3</sup> Neil Strotman,<sup>3</sup> and William J. Kerr<sup>1</sup>

<sup>1</sup>Department of Pure and Applied Chemistry, University of Strathclyde, Glasgow, G1 1XL, Scotland, U.K.

<sup>2</sup>Radiochemistry Section, Centre for Drug Discovery, RTI International, North Carolina, USA

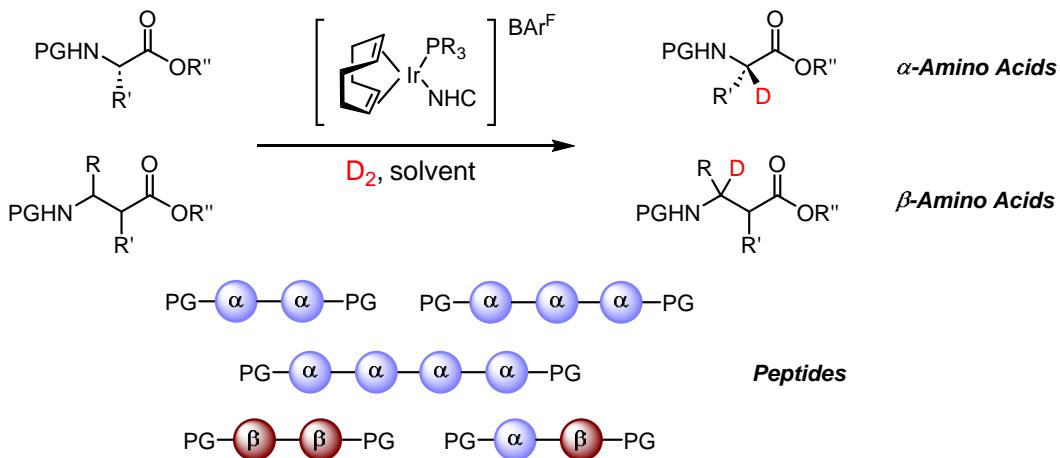
<sup>3</sup>Department of Process Research and Development, Merck & Co., Inc., Rahway, New Jersey 07065, USA

David.lindsay@strath.ac.uk

Hydrogen isotope exchange (HIE) has received considerable attention in recent years, with new methodologies focusing on the overall effectiveness and applicability in labelling pharmaceutically-relevant drug molecules and motifs. In particular, the Kerr group at Strathclyde has carried out extensive studies based on the development of a suite of Ir catalysts to facilitate directed labelling processes.<sup>1,2</sup> A number of previously challenging directing groups within aromatic molecules can now facilitate labelling using these Ir catalysts; however, directed HIE of C(sp<sup>3</sup>)-H bonds still remains challenging. With the pharmaceutical industry's continuing focus on developing molecules with increased sp<sup>3</sup> character, we have recently begun to explore HIE at C(sp<sup>3</sup>)-H bonds, including within saturated heterocycles and open-chain systems, directed by both N-heterocycles<sup>3</sup> and nitrogen-based carbonyl groups.<sup>4</sup>

In recent years, the pharmaceutical industry has targeted the exploration of the novel chemical space afforded by new drug modalities, with a particular renaissance in the area of peptides. Based on this, and building on our early C(sp<sup>3</sup>)-H labelling studies, we have expanded our Ir-catalysed methodology to the labelling of both  $\alpha$ - and  $\beta$ -amino acids, and peptides thereof. Herein, our approach to the labelling of these C(sp<sup>3</sup>)-H systems will be described.

Through optimisation, catalyst screening, and rationalisation of reactivity using DFT calculations, excellent deuterium incorporations have been demonstrated in a broad range of protected  $\alpha$ - and  $\beta$ -amino acids. Our approach has been extended to di-, tri- and tetra-peptides, including  $\alpha$ - only,  $\beta$ - only, and mixed  $\alpha,\beta$ -peptides, with residue-selectivity observed in many cases.



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## **Adventures in pharmaceutical catalysis**

Dr Katherine M Wheelhouse FRSC

GSK Medicines Research Centre, Gunnels Wood Road, Stevenage, Hertfordshire, SG1 2NY, UK

katherine.m.wheelhouse@gsk.com

Chemical catalysis is a key technology in chemical synthesis, including pharmaceutical manufacture. Application to manufacturing processes requires understanding of a range of factors beyond the reaction itself, from sourcing the specific catalyst required to understanding of the equipment, separation of the catalyst residues from the product and the equipment train and eventual recovery of the precious metal. This talk will cover two case studies from GSK where difference in oxygen levels between lab development and the plant resulted in a difference in performance, necessitating careful selection of the equipment for lab experiments to generate appropriate data to predict what would happen for future plant campaigns.

## Droplet-Based F-18 Radiolabelling Reactions

Dr Philip Miller  
Molecular Sciences Research Hub, White City Campus, U.K.  
[Philip.miller@imperial.ac.uk](mailto:Philip.miller@imperial.ac.uk)

Positron emission tomography (PET) is now a routinely used clinical imaging technique for the diagnosis and staging of cancer. PET imaging relies on the use of targeted radiopharmaceuticals that accumulate in specific tissues, and following decay via positron emission, enable the spatial and temporal imaging of these tracers in the body. The preparation of PET tracers is, however, a challenging area of (radio)chemistry owing to the short half-lives of the positron emitters: F-18 ( $t_{1/2} = 109$  min), C-11 ( $t_{1/2} = 20.4$  min), Ga-68 ( $t_{1/2} = 67.7$  min) and N-13 ( $t_{1/2} = 10.0$  min) that are typically used in the production of PET tracers. The short half-lives of such nuclides, coupled with the small molar quantities (sub-micromolar) that they are produced in, presents challenges of both time and scales of labelling processes. Reaction times are therefore typically restricted to minutes, and the overall volumes of reactions are often on the order of microlitres to millilitres. Consequently, chemical reactions that are kinetically fast, selective and efficient are highly attractive for such radiolabelling procedures with short-lived radionuclides; so too is technology such as microfluidics and other such miniaturised systems that can be automated and used to handle small volumes of radioactive material in a safe and controllable way. This presentation will discuss the adaptation of the aluminium  $[^{18}\text{F}]$ fluoride ( $[^{18}\text{F}]$ AIF) radiolabelling method to a microdroplet platform. The  $[^{18}\text{F}]$ AIF radiolabelling method has attracted considerable interest in recent years owing to its fast and mild reaction conditions, and its high labelling efficiencies. The strong aluminium-fluoride bonds and the ease of complexation of the  $[^{18}\text{F}]$ AIF $^{2+}$  ion by common chelators such as NOTA and NODA has enabled the labelling of clinically important biological molecules. Working in collaboration with colleagues at UCLA, we have developed a microdroplet radiolabelling method for  $[^{18}\text{F}]$ AIF labelling reactions. A model tetrazine analogue (NODA-Tz) displayed excellent radiolabelling performance (high radiochemical yields) with the microdroplet platform using only nanomolar quantities of precursor. Furthermore, the platform has been used to successfully prepare  $[^{18}\text{F}]$ AIF-FAPI-74, a clinically relevant imaging agent which targets the fibroblast activation protein and has potential applications for imaging different cancers.

## **Metallodrugs In The Hot Seat: Accelerating Preclinical Development With Radionuclide Imaging**

Dr Cinzia Imberti

Department of Imaging Chemistry & Biology, School of Biomedical Engineering and Imaging Sciences, King's College London, 3<sup>rd</sup> Floor Lambeth Wing, St. Thomas' Hospital, London, SE1 7EH, UK  
cinzia.imberti@kcl.ac.uk

Medicinal chemistry extends beyond organic chemistry — so far compounds from more than 50 metals have been investigated clinically for medical purposes, from universally known chemotherapeutics such as platinum drugs to less familiar agents explored for their diagnostics and (radio)therapeutics properties. Interestingly, several of these metals have one or more radioisotopes whose emission are appropriate for radionuclide imaging studies, thus providing a powerful tool to investigate in their biological behaviour by developing their radiolabeled version and use it to investigate their speciation and *in vivo* biodistribution. In this presentation, I will discuss examples of how we have used radionuclide imaging and radioanalytical techniques to understand distribution and mechanism of action of metallodrugs at different development stage, from clinically relevant chemotherapeutics to novel photoactivatable agents. I will highlight the challenges and opportunities that this approach presents and how it can be leveraged to accelerate the preclinical development of novel metallodrugs towards clinical translation.

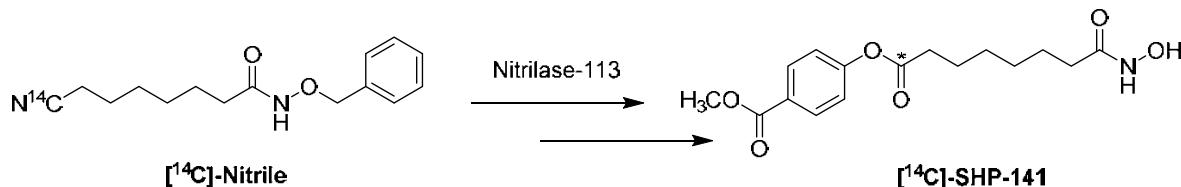
## **Application Of Nitrilase In [<sup>14</sup>C]-SHP-141 Synthesis: Advancing Remetinostat, An HDAC Inhibitor**

Dr. Sean L. Kitson

Almac, Department of Technology, Craigavon, BT63 5QD, UK,  
sean.kitson@almacgroup.com

In this conference presentation, we will discuss the radiolabelling strategy for the synthesis of [<sup>14</sup>C]SHP-141 (Remetinostat), a histone deacetylase (HDAC) inhibitor for treatment of inflammatory and hyper-proliferative diseases of the skin.

The key step in the radiosynthesis was the conversion of the [<sup>14</sup>C]-nitrile directly into the [<sup>14</sup>C]-carboxylic derivative using nitrilase-113 biocatalyst. The final step involved deprotection of the benzyloxy group using catalytic hydrogenation to facilitate the release of the hydroxamic acid without cleaving the phenoxy ester. [<sup>14</sup>C]SHP-141 was isolated with a radiochemical purity of 90% and a gravimetric specific activity of 190 µCi/mg in four radiochemical steps starting from potassium [<sup>14</sup>C]-cyanide with an overall in a radiochemical yield of 45%.



We believe that our innovative approach holds the potential to enhance the synthesis of other carbon-14-labelled compounds and make a significant impact in the field of radiochemistry. During the presentation, we will discuss each step of the radiosynthesis, discussing the advantages, challenges, and potential applications of our novel strategy.

### **References**

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## Poster Abstracts

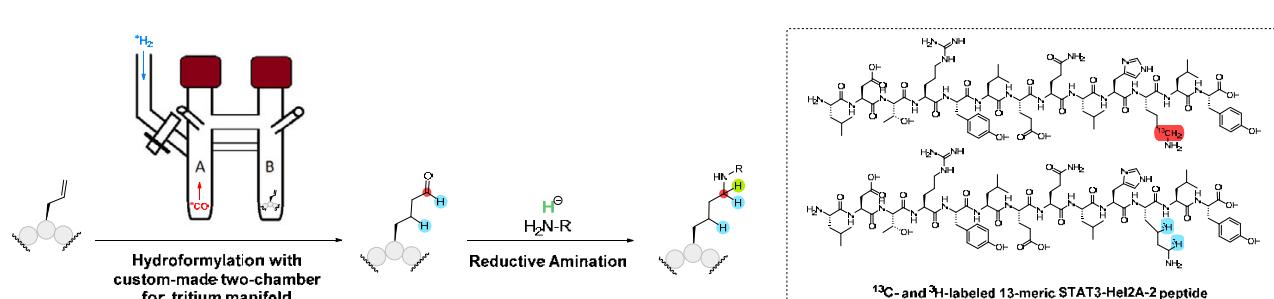
# LATE-STAGE $^{14}\text{C}$ / $^3\text{H}$ -ISOTOPIC LABELING AND SITE-SELECTIVE MODIFICATION OF PEPTIDES VIA FORMATION OF ALLYSINE IN A HYDROFORMYLATION REACTION

Anika Schick<sup>[a,c]</sup>, Kim Saskia Mühlfenzl<sup>[a]</sup>, Hans Christian Dahl Hammershøj<sup>[c]</sup>, Johan Broddefalk<sup>[b]</sup>, Ranganath Gopalakrishnan<sup>[b]</sup>, Troels Skrydstrup<sup>[c]</sup>, Charles S Elmore<sup>[a]</sup>

<sup>[a]</sup>Early Chemical Development, Pharmaceutical Sciences, R&D, AstraZeneca, Gothenburg, Sweden

<sup>[b]</sup>Medicinal Chemistry, Research and Early Development, Cardiovascular, Renal and Metabolism, BioPharmaceuticals R&D, AstraZeneca, Gothenburg, Sweden

<sup>[c]</sup>Interdisciplinary Nanoscience Center (iNANO) and Department of Chemistry, Aarhus University, Denmark  
anika.schick@astrazeneca.com



In recent years, peptide drug development has made great progress. To investigate the adsorption, distribution, metabolism, and excretion (ADME) of therapeutic peptides more in-depth,  $^{14}\text{C}$ - and  $^3\text{H}$ -labeled analogs are needed. Effective late-stage labeling methods to obtain the native radiolabeled peptide are desired to limit the radioactive material used. However, such methods are not well developed yet. In this poster, we describe the development of a new late-stage labeling strategy for peptides using hydroformylation with syngas ( $\text{H}_2$  and  $\text{CO}$ ) on solid support. This reaction is performed in a custom-made two-chamber system for *ex-situ* formation of carbon monoxide<sup>1</sup> and enables the attachment to a tritium manifold. Reductive amination of the resulting aldehyde with an amine and subsequent deprotection and cleavage from the resin yields the labeled natural amino acid lysine or a lysine derivative. Noteworthy, this method can be used for both  $^{14}\text{C}$ - and  $^3\text{H}$ -labeling. The method was applied to different peptides, such as the peptide hormone Somatostatin (14-mer, cyclic), the backbone of the peptide therapeutic Semaglutide (31-mer), and the STAT3 inhibitor STAT3-Hel2A-2 (13-mer). STAT3-Hel2A-2-[ $^{13}\text{C}$ ] was obtained in 51% yield using 5 equiv. of  $^{13}\text{CO}/\text{H}_2$ . In addition, it was successfully labeled with tritium, resulting in 338 MBq of STAT3-Hel2A-2-[ $^3\text{H}$ ] using 45 equiv.  $\text{CO}/^3\text{H}_2$ . In conclusion, this new application of the hydroformylation reaction on peptides provides a way for the late-stage radiolabeling of therapeutic peptides and to site-selectively label lysine residues.

## References

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# IRIDIUM CATALYSED ARYL HYDROGEN ISOTOPE EXCHANGE DIRECTED BY BENZYLIC AMINES

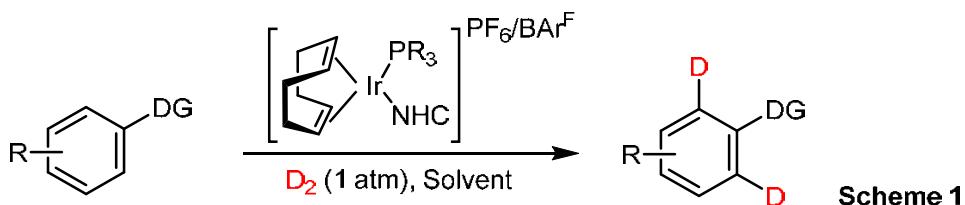
David M. Lindsay<sup>a</sup>, James D. F. Thompson<sup>b</sup>, Liam P. Raeside<sup>a</sup>, Michael Field<sup>a</sup>, Nathan M. L. Knight<sup>a</sup>, and William J. Kerr<sup>a</sup>

<sup>a</sup>Department of Pure and Applied Chemistry, University of Strathclyde, Glasgow, G1 1XL, Scotland (U.K.)

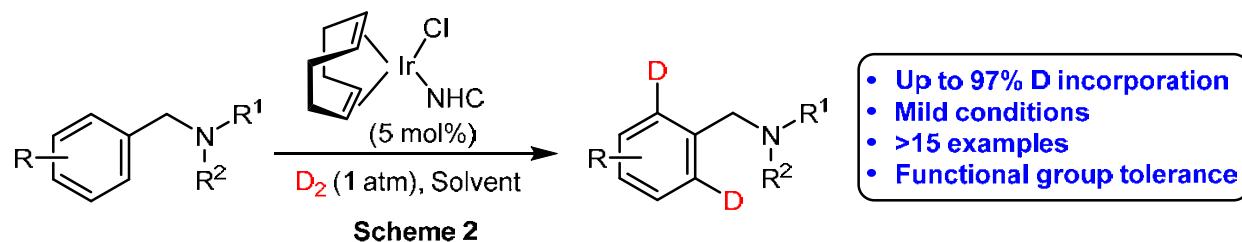
<sup>b</sup>Medicinal Chemistry, GSK Medicines Research Centre, Gunnels Wood Road, SG1 2NY, Stevenage, England (U.K.)

liam.raeside.2017@uni.strath.ac.uk

Absorption, distribution, metabolism, excretion, and toxicity (ADMET) studies are essential to the assessment of pharmacokinetics and pharmacodynamics of emerging drug candidates. These studies rely on isotopically labelled analogues, which allow incorporation of a traceable label without significantly altering the physical properties of the compound.<sup>1</sup> Late-stage hydrogen isotope exchange (HIE) has been explored to furnish selectively labelled molecules without expensive and time-consuming re-synthesis of labelled analogues.<sup>2</sup> Iridium(I) catalysts of the type  $[\text{Ir}(\text{COD})(\text{PR}_3)(\text{NHC})]\text{X}$ , extensively developed within our laboratories,<sup>3</sup> have proven to be highly active HIE catalysts, operating under mild conditions, and utilising a variety of directing groups for the C-H activation required for HIE (Scheme 1).



Benzylic amines are crucial motifs in a wide range of fields, including pharmaceuticals, organic building blocks, and in polymer chemistry. Considering the widespread utility of this functionality, C–H activation directed by the benzylic amine functionality would be particularly useful for late-stage functionalisation reactions, including HIE. However, examples of the *ortho*-directed HIE of secondary or tertiary benzylic amines are extremely rare and either require harsh reaction conditions with high catalyst loadings or have very limited substrate scopes.<sup>4</sup> This work describes the application of pharmaceutically-ubiquitous benzylic amines for directed C(sp<sup>2</sup>)-H functionalisation using a neutral Iridium(I) chloro-carbene complex (Scheme 2). This methodology has been applied to a range of benzylic amines, containing a variety of aryl substituents, giving high levels of deuterium incorporation. Notably, the scope includes Lewis basic functionality known to be competent as directing groups in HIE using cationic iridium(I) catalysts of the type  $[\text{Ir}(\text{COD})(\text{PR}_3)(\text{NHC})]\text{X}$ . Reaction optimisation will be described, along with competition studies related to other Lewis basic functionality.



- Up to 97% D incorporation
- Mild conditions
- >15 examples
- Functional group tolerance

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# **MASS BALANCE RECOVERY, ABSORPTION, METABOLISM, AND EXCRETION OF [<sup>14</sup>C]-ACOZIBOROLE IN HEALTHY MALE SUBJECTS AFTER SINGLE MICROTRACER ORAL DOSING – I – PREPARATION OF GMP [<sup>14</sup>C]-ACOZIBOROLE DRUG SUBSTANCE**

S. Rembry,<sup>a</sup> J.-Y. Gillon,<sup>a</sup> S. Robinson,<sup>a</sup> I. Shaw,<sup>b</sup> P. Cousin,<sup>c</sup> D. Carver<sup>c</sup>

<sup>a</sup>DNDi

<sup>b</sup>Quotient

<sup>c</sup>Selcia

Acoziborole (Figure 1), an oxaborole-6 carboxamide, is being developed as an oral single dose treatment for Human African trypanosomiasis (also called "sleeping sickness"). As part of the overall development programme the mass balance, pharmacokinetics, metabolism and excretion of acoziborole were studied in an open-label, clinical phase 1 study in 6 healthy male subjects.

This poster will describe the radiolabelling and purification of [<sup>14</sup>C]-acoziborole as a GMP radiolabelled Drug Substance to support the human metabolism investigation. The mass balance and clinical safety assessments and the metabolite characterisation investigations are described in separate posters.

A typical process for GMP [<sup>14</sup>C]-Drug Substance purification is described in Figure 2.

The synthesis of non-GMP [oxaborol-3-<sup>14</sup>C]-acoziborole, the designated radiolabelled starting material supplied by the Sponsor, is described starting from barium [<sup>14</sup>C]-carbonate. A risk assessment of the TSE/BSE status of the supplied [oxaborole-<sup>14</sup>C]-acoziborole was conducted based on information relating to its original manufacture and provenance.

[<sup>14</sup>C]-Acoziborole drug substance was repurified at high specific activity (HSA) from the radiolabelled precursor [<sup>14</sup>C]-acoziborole using preparative-HPLC. An aliquot was held in storage at -20 °C for use in the GMP [<sup>14</sup>C]-Drug Substance preparation. Radiochemical dilution using non-radiolabelled Drug Substance provided [<sup>14</sup>C]-acoziborole at medium specific activity (MSA) for use in stability studies. The MSA batch was subjected to three further sequential dilutions to provide a low specific activity (LSA3) technical batch for a trial Drug Product (IMP) manufacture at Quotient Sciences. Recrystallisation was confirmed to give the desired physical form (Form B).

The validated HPLC chemical purity and assay method used was formally transferred from DNDi and adapted for GMP [<sup>14</sup>C]-Drug Substance release and radio-stability testing. MSA [<sup>14</sup>C]-acoziborole showed that the product was stable for at least 4 weeks, both at -20 °C and at -80 °C.

Repurification was performed in a dedicated GMP radiosynthesis laboratory starting from retained [<sup>14</sup>C]-acoziborole to provide GMP [<sup>14</sup>C]-acoziborole. QC analysis and QA review of the batch record confirmed the required specifications had been met.

This radiosynthesis and GMP repurification process provided the necessary supply of GMP [<sup>14</sup>C]-Drug Substance required to support Drug Product manufacture and regulatory submission for a human AME study with acoziborole in a time and material efficient manner.

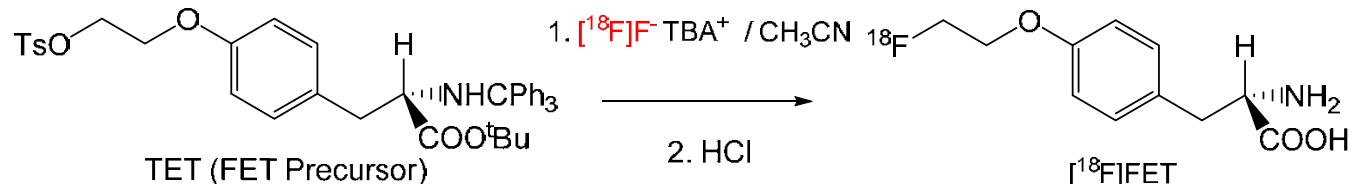
# PRODUCTION OF [<sup>18</sup>F]-O-(2-FLUOROETHYL)-L-TYROSINE ON GE FASTLAB 2 IN A GMP ENVIRONMENT

Matthew Hird, Bethany Scattergood, Aniruddha Doke and Graham Smith

Radiopharmaceutical Unit, Wolfson Brain Imaging Centre, School of Clinical Medicine, University of Cambridge, UK  
mh910@cam.ac.uk

**Introduction:** [<sup>18</sup>F]-O-(2-Fluoroethyl)-L-tyrosine, or [<sup>18</sup>F]-FET is a radiotracer currently under validation at the Radiopharmaceutical Unit (RPU). [<sup>18</sup>F]-FET PET has been applied to clinical differentiation between brain tumours and non-neoplastic lesions in both children and adult patients. It has also been used to distinguish between low/high grade gliomas via PET imaging.

**Materials And Methods:** The GE FASTlab 2 is used for the synthesis of [<sup>18</sup>F]-FET via cartridge purification. [<sup>18</sup>F]-Fluoride is produced from the GE PETtrace 800 cyclotron in 20-25 min. irradiation producing 45 GBq starting radioactivity. The radiosynthesis of [<sup>18</sup>F]FET proceeds via nucleophilic [<sup>18</sup>F]fluorination of the TET precursor (7 mg) in acetonitrile, heated at 135 °C for 10 minutes with [<sup>18</sup>F]Fluoride (previously azeotropically dried). The solution is cooled to 100 °C and the remaining MeCN evaporated. The protected [<sup>18</sup>F]FET is then deprotected to produce [<sup>18</sup>F]-FET via acid hydrolysis. Afterwards, the reaction mixture is mixed in a syringe with 3 mL of water and is passed through the, in series WAX® (yellow ring), 2 x HLB® (grey ring) reversed-phase sorbent cartridges to trap [<sup>18</sup>F]FET. The reactor is rinsed with further 5 mL of water to collect the residual product which is then passed through the trapping cartridges. The cartridges are rinsed with water for injection (WFI) to wash off solvents and unreacted free [<sup>18</sup>F]fluoride ions and impurities into the external waste bottle. [<sup>18</sup>F]FET is eluted from the cartridges with ~6 mL of 5% aqueous EtOH solution and passed through a series of CM and Light Alumina N cartridges for final purification. This step is repeated twice followed by formulation by passing through the cartridges ~3 mL of buffer solution.



**Scheme 1.** Radiosynthesis of [<sup>18</sup>F]-FET

**Results:** Currently 4 validation runs have been completed. Typical synthesis time was 58 minutes and average radiochemical yield was 45% ± 5 (n = 3, non-corrected). This provides ~8 GBq for patient use, sufficient for extensive imaging studies on site.

**Conclusions:** [<sup>18</sup>F]-FET has been validated for clinical production in RPU. The manufacturing process is robust, fully-automated with minimal user interaction and provides enough radiotracer for 3-6 patients doses on site.

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# INVESTIGATIONS INTO NEW CHEMICAL TOOLKITS FOR DRUG DISCOVERY, SENSING AND CELLULAR IMAGING APPLICATIONS

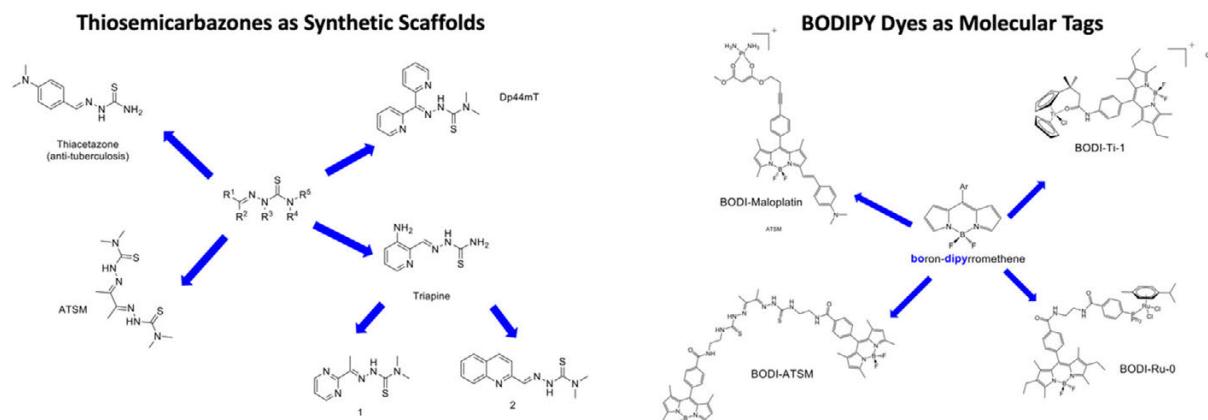
Megan Green, Charareh Pourzand, and Sofia I. Pascu\*

Department of Chemistry, University of Bath, Claverton Down, BA2 7AY

**Abstract:** This work aims to address limitations of current diagnostic methods for prostate cancer (PCa) and explore emerging optical imaging technologies in this context. This project focuses on developing hybrid inorganic-organic as emissive metal complexes towards targeted theranostic platforms designed to enhance PCa cellular uptake and localisation. This approach is a key part in our multidisciplinary approach in theranostics development which is grounded in the state-of-the-art (**Figure 1**)<sup>1-4</sup> and built around two core objectives:

**Optimizing Cellular Uptake and Localisation:** We aim to deepen our understanding of cellular internalization mechanisms for novel probes, using metallomics to map metal ion speciation and enhance probe efficiency and specificity.

**Validating Probe Efficacy and Stability:** We are developing methods to monitor probe transformations within cells, in alignment with cytotoxicity assessments like MTT and LDH assays, to establish reliability and safety standards for our theranostic platforms.



**Figure 1:** State-of-the art and scaffolds for molecules of interest

Specifically, we report hereby our investigation into the potential of new thiosemicarbazones (TSCs) to act as anti-neoplastic agents, alongside novel BODIPY-based imaging agents for dual diagnostic and therapeutic (theranostic) purposes. The synthesis of TSC ligands with varied heterocyclic structures and distinct functional groups is outlined, followed by evaluation of their anti-neoplastic effects in PC-3 cells using MTT assays. Additionally, new as-synthesised BODIPY-TSC derivatives are discussed alongside an examination of their photophysical properties. Preliminary assessments in their cellular interactions through fluorescence imaging and colocalisation in PC-3 cells are showcased. Overall, this work marks a step towards the development of advanced theranostic probes that could offer greater precision and effectiveness in early prostate cancer detection.

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# ARYL HALIDE CARBOXYLATION VIA DECARBOXYLATIVE METAL-HALOGEN EXCHANGE

Daniel J. Ryder-Mahoney,<sup>a</sup> Katherine Marris,<sup>a</sup> Charles S. Elmore,<sup>b</sup> Ryan A. Bragg,<sup>c</sup> Ken Yamazaki<sup>d</sup> and Gregory J. P. Perry<sup>a</sup>

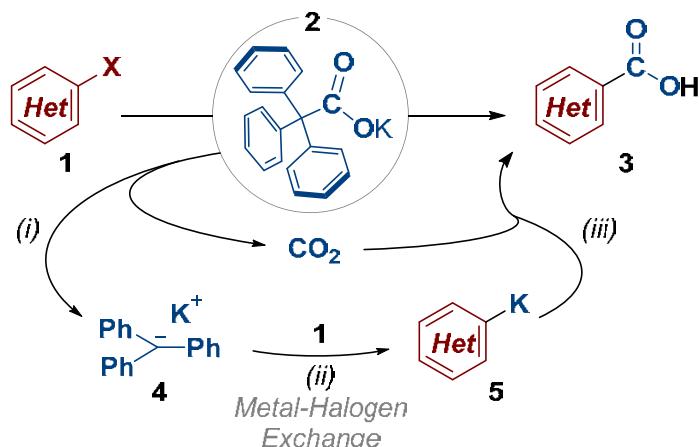
<sup>a</sup>School of Chemistry, University of Southampton, Southampton, SO17 1BJ, UK.

<sup>b</sup> Early Chemical Development, Pharmaceutical Sciences, R&D, AstraZeneca, Gothenburg, Sweden.

<sup>c</sup> Early Chemical Development, Pharmaceutical Sciences, R&D, AstraZeneca, Cambridge, UK.

<sup>d</sup> Division of Applied Chemistry, Okayama University, Okayama, 700-8530, Japan.

E-mail: djrm1u23@soton.ac.uk, km1g20@soton.ac.uk, gregory.perry@soton.ac.uk



**Scheme 1:** The carboxylation of aryl halides **1** by dual-function reagents **2**.

Carboxylic acids are widely used across multiple industries, including the pharmaceutical and agrochemical sectors, with numerous applications as synthetic building blocks or desired products. Routes for carboxylating aryl halides are known but often involve hazardous organometallic reagents that require specialised handling, or expensive transition metal catalysts.<sup>1,2</sup> In addition, gaseous CO<sub>2</sub> is generally used in excess which limits the direct application of these processes in isotopic labelling.<sup>3</sup> The controlled delivery of CO<sub>2</sub> in an efficient manner would provide a useful tool in the arena of carbon isotope chemistry.

We present a unique mode of metal-halogen exchange for the carboxylation of heteroaromatic halides by the potassium salt of triphenylacetic acid **2** (Scheme 1). We describe the carboxylate **2** as a dual-function reagent because it performs as a combined source of CO<sub>2</sub> and metalating agent.<sup>4</sup> Mechanistic studies support our proposed decarboxylative metal-halogen exchange in which the dual-function reagent **2** initially undergoes decarboxylation to give the metalating agent **4** and CO<sub>2</sub> (step i) followed by metal-halogen exchange with the aryl halide substrate **1** (step ii). The metalated intermediate **5** then captures the in situ generated CO<sub>2</sub> to provide the desired carboxylated product **3** (step iii). The reaction provides a practical route for delivering labelled CO<sub>2</sub> as it proceeds under mild conditions, uses just a slight excess of a weighable, bench-stable labelling reagent **2**, and does not require pressurised apparatus.

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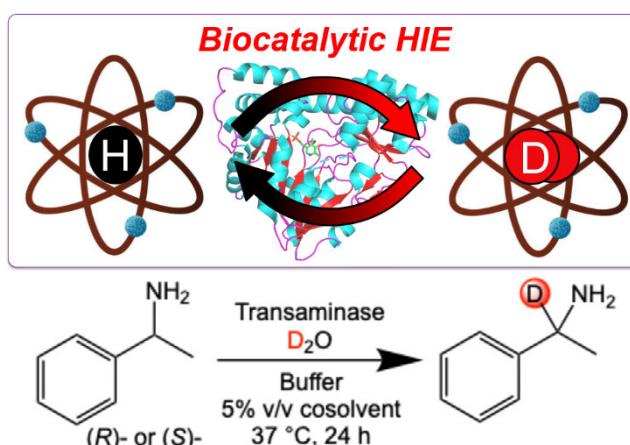
# BIOCATALYTIC HIE FOR THE SYNTHESIS OF DEUTERATED PHARMACEUTICALS

Christopher W. Otun,<sup>1,\*</sup> Francesco Falcioni,<sup>2</sup> Ryan A. Bragg,<sup>2</sup> Charles S. Elmore<sup>3</sup> and Jack S. Rowbotham<sup>1</sup>

Department of Chemistry, Manchester Institute of Biotechnology, University of Manchester, Manchester, M1 7DN, UK; <sup>2</sup>Early Chemical Development, Pharmaceutical Sciences, R&D, AstraZeneca, Cambridge, UK; <sup>3</sup>Early Chemical Development, Pharmaceutical Sciences, R&D, AstraZeneca, Gothenburg, Sweden.

\*christopher.otun@postgrad.manchester.ac.uk

The deuterium kinetic isotope effect (DKIE) can be exploited to increase the therapeutic value of pharmaceuticals, which can suffer from rapid oxidation or racemisation *in vivo*. By decreasing the rate of these attrition reactions using the DKIE, deuterated drugs can be administered in lower dosages and remain active in the body for longer durations compared to their undeuterated counterparts.<sup>1</sup> Thus, the interest in deuterated pharmaceutical agents has increased substantially in recent years, provoking the development of a range of chemical methods for their synthesis. Biocatalysis is a valuable option for installing deuterium atoms at targeted locations, because enzymes are naturally selective, and operate in aqueous conditions (enabling D<sub>2</sub>O to be used as solvent and isotope source).<sup>2</sup> Whilst reductive methods for biocatalytic deuteration have been shown, hydrogen isotope exchange (HIE), which is very common in chemocatalytic isotopic labelling, is not well developed for enzymes. This poster presents data on new approaches for enzymatic HIE. By capitalising on micro-reversibility in the catalytic cycles of various enzymes (such as flavoenzymes and PLP-dependent enzymes) deuterium can be installed at selected sites under easily implemented reaction conditions. For example, PLP-dependent transaminases can be employed for hydrogen isotope exchange to give  $\alpha$ -deuteration of chiral amines with full stereo-retention (Figure 1). The poster will present emerging applications of enzymatic HIE, which will help to enable the synthesis of deuterated drugs for research, diagnostics, and therapeutic applications.



**Figure 1** Biocatalytic HIE can be used to install deuterium at selected asymmetric centres, as demonstrated by the  $\alpha$ -deuteration of (R)- and (S)-1-phenylethylamine by different transaminases in D<sub>2</sub>O.

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Groningen  
The Netherlands

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Tel: +31(0)6.15222239  
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[www.revvity.com](http://www.revvity.com)

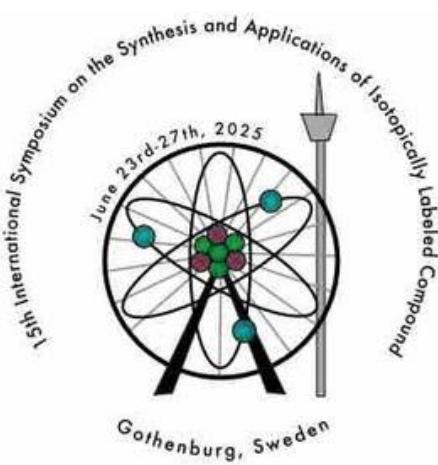
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<b>Delegate</b>	<b>Organisation</b>	<b>Email address</b>
Mr Andrew Baker	Advion-Interchim	andy.baker@advion-interchim.com
Dr Mark Allen	Advion-Interchim	mark.allen@advion-interchim.com
Dr Bala Upeandran	Almac Group Ltd	bala.upeandran@almacgroup.com
Dr Sean Kitson	Almac Group Ltd	sean.kitson@almacgroup.com
Dr Chad Elmore	Astrazeneca	chad.elmore@astrazeneca.com
Dr Måns Andreasson	AstraZeneca	mans.andreasson@astrazeneca.com
Dr Pablo Martinez Pardo	AstraZeneca	pablo.martinezpardo@astrazeneca.com
Dr Ryan Bragg	AstraZeneca	ryan.bragg@astrazeneca.com
Ms Anika Schick	AstraZeneca	anika.schick@astrazeneca.com
Dr Kim Mühlfenzl	AstraZeneca	kimsaskia.muehlfenzl@astrazeneca.com
Mr Jonas Bergare	AstraZeneca	jonas.bergare@astrazeneca.com
Dr Arran Solomonsz	Asynt Ltd	arran.solomonsz@asynt.com
Mr Ed Holden	Berthold Technologies	ed.holden@Berthold.com
Ms Laura Ford-Ramsden	Biocair International	laura.ford-ramsden@biocair.com
Mr Shane Iles	Biocair International	shane.iles@biocair.com
Mr Gary Wicksted	Charles River	gary.wicksted@crl.com
Dr Amy Edo-Osagie	Eurofins Selcia	amy.edo-osagie@selcia.com
Dr Chris Winfield	Eurofins Selcia	chris.winfield@selcia.com
Mr David Carver	Eurofins Selcia	david.carver@selcia.com
Dr James Grayson	Eurofins Selcia	james.grayson@selcia.com
Dr Philip Hope	Eurofins Selcia	philip.hope@selcia.com
Dr Rafael Bou Moreno	Eurofins Selcia	rafael.boumoreno@selcia.com
Dr Rhys Lippa	Eurofins Selcia	rhys.lippa@selcia.com
Dr Richard Scott	Eurofins Selcia	richard.scott@selcia.com
Dr Robert Mack	Eurofins Selcia	robert.mack@selcia.com
Dr Saikiran Ravi	Eurofins Selcia	saikiran.ravi@selcia.com
Dr Shweta Gediya	Eurofins Selcia	shweta.gediya@selcia.com
Dr Stephen Roe	Eurofins Selcia	stephen.roe@selcia.com
Dr Martin R. Edelmann	F. Hoffmann-La Roche Ltd	martin.edelmann@roche.com
Mr Mathias Mueller	F. Hoffmann-La Roche Ltd	mathias.mueller@roche.com

<b>Delegate</b>	<b>Organisation</b>	<b>Email address</b>
Dr Daniela Roman	GlaxoSmithKline	daniela.x.roman@gsk.com
Dr Geoff Badman	GlaxoSmithKline	geoff.t.badman@gsk.com
Dr Hannah Broderick	GlaxoSmithKline	hannah.c.broderick@gsk.com
Dr Katherine Wheelhouse	GlaxoSmithKline	katherine.m.wheelhouse@gsk.com
Mr Nick Shipley	GlaxoSmithKline	nick.j.shipley@gsk.com
Ms Sarosh Ali	GlaxoSmithKline	sarosh.a.ali@gsk.com
Mr Ian Lawrence	Goss Scientific	ian@gossinst.co.uk
Mr Jonathan Bell	Goss Scientific	jonathan@gossinst.co.uk
Dr Philip Miller	Imperial College London	philip.miller@imperial.ac.uk
Mr Steve Brough	Key Organics Limited	steveb@keyorganics.net
Dr Cinzia Imberti	King's College London	cinzia.imberti@kcl.ac.uk
Dr Graeme Stasiuk	King's College London	graeme.stasiuk@kcl.ac.uk
Ms Libby Barlow-Hall	LabLogic Systems Ltd.	ebarlow-hall@lablogic.com
Mr Roy Corner	LabLogic Systems Ltd.	rcorner@lablogic.com
Dr Helen Betts	Nottingham University Hospitals NHS Trust	helen.betts@nottingham.ac.uk
Mr Matti Vaismaa	Orion Pharma	Matti.Vaismaa@orionpharma.com
Dr Andrew Watson	Pharmaron UK	andrew.watson@pharmaron-uk.com
Mr Bruce Brown	Pharmaron UK	bruce.brown@pharmaron-uk.com
Dr Judith Smith	Pharmaron UK	judith.smith@pharmaron-uk.com
Ms Marta Pakiet	Pharmaron UK	pakiet.marta377@gmail.com
Dr Mubarak Dambatta	Pharmaron UK	mubarak.dambatta@pharmaron-uk.com
Dr Neil Smith	Pharmaron UK	Neil.Smith@Pharmaron-uk.com
Dr Siôn Edwards	Pharmaron UK	sion.edwards@pharmaron-uk.com
Dr Stuart Phillips	Pharmaron UK	stuart.phillips@pharmaron-uk.com
Mr Shen Guangzi	Porse Fine Chemical Co.,Ltd	info@porsefinechemical.com
Mr Andrew Ditchman	Qmx Laboratories Limited	aditchman@qmx.com
Dr Alan Jeuken	Quotient Sciences	alan.jeuken@quotientsciences.com
Dr Andrew Kohler	Quotient Sciences	andrew.kohler@quotientsciences.com
Mr Iain Shaw	Quotient Sciences	iain.shaw@quotientsciences.com
Mr Devi Seijkens	Revvity	devi.seijkens@revvity.com
Ms Megan Green	University of Bath	mjg80@bath.ac.uk
Professor Chris Willis	University of Bristol	chris.willis@bristol.ac.uk
Professor Franklin Aigbirhio	University of Cambridge	fia20@medsch.cam.ac.uk
Dr Graham Smith	University of Cambridge	gs739@cam.ac.uk

<b>Delegate</b>	<b>Organisation</b>	<b>Email address</b>
Dr Matthew Hird	University of Cambridge	mh910@cam.ac.uk
Mr Christopher Otun	University of Manchester	christopher.otun@postgrad.manchester.ac.uk
Dr Jack Rowbotham	University of Manchester	jack.rowbotham@manchester.ac.uk
Dr Gregory Perry	University of Southampton	gregory.perry@soton.ac.uk
Mr Siyuan Wang	University of Southampton	sw5u24@soton.ac.uk
Ms Katherine Marris	University of Southampton	km1g20@soton.ac.uk
Dr David Lindsay	University of Strathclyde	david.lindsay@strath.ac.uk
Mr Liam Raeside	University of Strathclyde	liam.raeside.2017@uni.strath.ac.uk
Dr Ksenia Stankevich	University of York	ksenia.stankevich@york.ac.uk
Professor Jason Holland	University of Zurich	jason.holland@chem.uzh.ch



# 15<sup>th</sup> International Symposium on the Synthesis & Applications of Isotopically Labeled Compounds

**Gothenburg, Sweden**  
**23<sup>rd</sup>-27<sup>th</sup> June 2025**

## Plenary Speakers



**Phil  
Baran**

Scripps Research  
Institute  
(remote)



**Veronique  
Gouverneur**

University  
of Oxford



**Matthias  
Beller**

Leibniz-Institut für  
Katalyse (LIKAT)  
University of Rostock



**Daniele  
Leonori**

RWTH Aachen  
University



**Tanja  
Gulder**

Saarland University  
Helmholtz Institute for  
Pharmaceutical Research  
Saarland (HIPS)



## Sessions (tentative)

Isotopic hydrogen  
Deuterium  
Carbon  
Analytical  
Drug Metabolism  
Biologics

Clinical studies  
Agrochemicals  
PET/Spect  
Young Chemist  
Poster session

Hosted on the AstraZeneca Campus

## Organisers

**Ryan Bragg**  
AstraZeneca  
Cambridge, UK

**David Hesk**  
Research Triangle Institute  
Raleigh, NC USA

**Chad Elmore**  
AstraZeneca  
Gothenburg, Sweden



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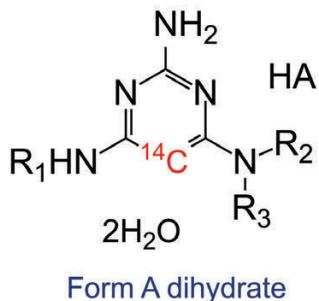
## <sup>14</sup>C Radiolabelling

- Non-GMP & GMP stable & radiolabelling expertise
- <sup>14</sup>C labelling of drug substance for human AME studies
- Stable & radiolabelled metabolite synthesis
- Specialist expertise in peptide & bioconjugate <sup>14</sup>C labelling
- QC, Analytical & QA integration
- MHRA regulatory approved for <sup>14</sup>C GMP manufacture of drug substance



# Case Studies

## Case Study 1 – $^{14}\text{C}$ GMP small molecule manufacture

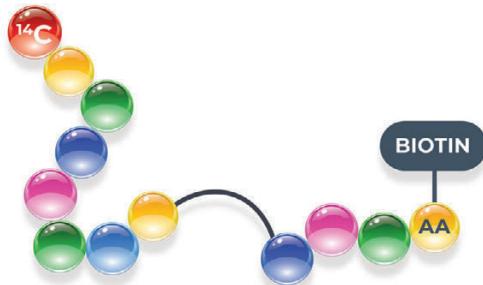


Our client required 3 mCi [ $^{14}\text{C}$ ]-Drug substance as Form A (dihydrate)

### The Almac Solution involved:

- GMP manufacture of the API, release analysis and completion of a stability study
- Desired polymorph was isolated via controlled crystallisation, drying, milling and controlled hydration
- Physical form of drug substance was confirmed by X-ray powder diffraction (XRPD)

## Case Study 2 – $^{14}\text{C}$ synthesis of biotinylated 84mer peptide



Our client required 2 mg of  $^{14}\text{C}$  labelled peptide

### The Almac Solution involved:

- Integration of peptide and radiolabelling teams
- Redesign of the coupling step to minimise loss of expensive labelled amino acid

## Case Study 3 – $^{14}\text{C}$ labelled PDC manufacture

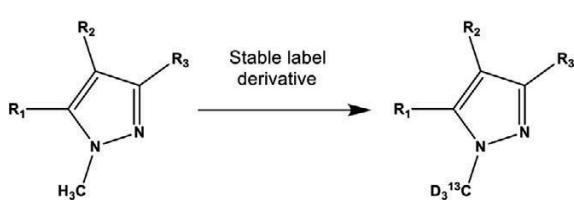


Our client required  $^{14}\text{C}$  labelling of the linker technology followed by formation of the PDC

### The Almac Solution involved:

- Integration of biology, purification and radiolabelling teams
- Prep-HPLC, HIC chromatography and ultrafiltration purification expertise

## Case Study 4 – $^{13}\text{CD}_3$ labelling



Our client required 250 mg of  $^{13}\text{CD}_3$  labelled material

### The Almac Solution involved:

- Non-GMP synthesis of stable labelled product
- Prep HPLC purification expertise
- Isotopic purity determination by Mass Spectrometry to determine levels of isotopomers / unlabelled material

Low temperature evaporation  
for even high-boiling solvents



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also suitable for larger lab reactors



CondenSyn air condensers

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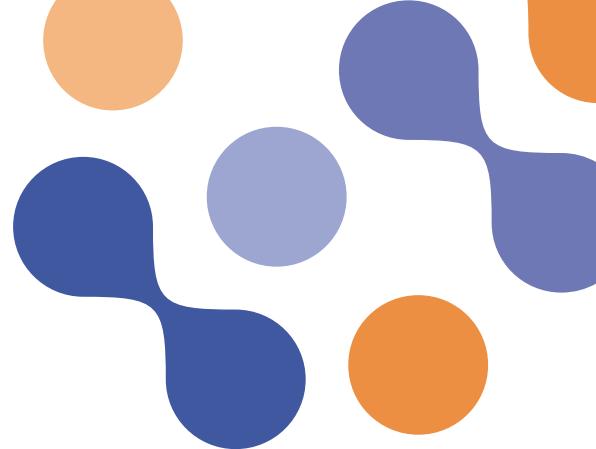
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- Support with regulatory documentation
- Export/Import expertise
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# Our Services

**<sup>14</sup>C Custom Radiosynthesis**

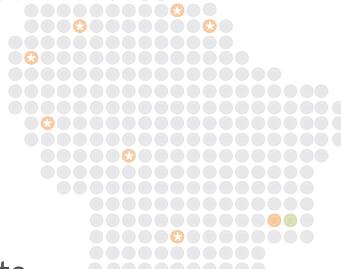
**GMP Radilabelled API for Clinical Trials**

**Stable Labelling / <sup>13</sup>C, <sup>2</sup>H, <sup>15</sup>N Metabolites and Impurities**

**GLP Analytics / GLP NMR**

**Radiolabelling to support Life Sciences:**

- Metabolism
- Distribution
- Mass Balance
- Micro-dosing
- Environmental fate
- Dermal Penetration



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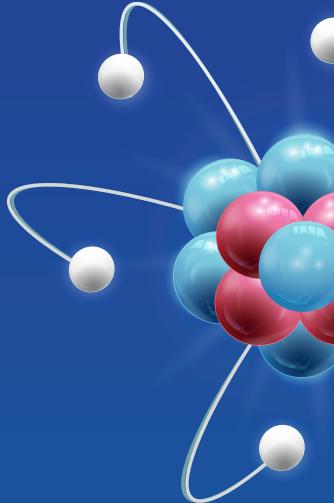
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- NMR Solvents
- Wilmad Labglass
- Lab Equipment



- Ultra-high Purity Gases
- Gas Mixtures
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- Lab Gas Installations



# Solutions for LSC and radio-HPLC



Laura™

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Laura software has long been considered the industry-standard software for instrument control and data collection for radiochromatography, now it provides a simple, easy to use and regulatory compliant solution for LSC.

For the 600 SLe and 300 SL, Laura software offers:

- Ability to meet GLP/GMP, MHRA and FDA 21 CFR part 212 / 11 requirements.
- Audit trail, electronic signatures and multi-level security.
- A simple, user-friendly system employing wizards for ease of use.
- Familiar ribbon-style used in Microsoft office applications.
- Windows 10 support and Easy copy/paste in Word, Excel and Powerpoint.
- Chain of ownership of all instrument data collection features.

# Beta-RAM™

The world's leading radio flow detector for HPLC offers unrivalled sensitivity, resolution and versatility.



With over 30 years of development and used by thousands of researchers worldwide, the Beta-RAM™ radio flow detector for HPLC coupled with the industry standard Laura radiochromatography software, leads the way for radiochromatographers.

## Logi-CHROM™ HPLC

Logi-CHROM™ HPLC modules, are a new addition to LabLogic's radiochromatography range. Compact, cost effective and fully integrated within Laura software, Logi-CHROM™ is available as a standard HPLC or UHPLC.

The new Logi-CHROM™ instruments are designed to meet your everyday challenges with versatility and reliability. These systems are flexible in many ways, offering a range of materials, flow rates and complexity levels. Logi-CHROM™ accomplishes your demanding analytical tasks with a selection of detectors, pumps, and columns.



## Hidex 600 SLe

Designed to meet the needs of laboratories processing large quantities of samples, the Hidex 600 SLe is a high throughput automatic TDCR liquid scintillation counter.

Using the robust and unique triple-to-double coincidence ratio (TDCR) counting technology from the successful 300 SL series, coupled with added sample capacity for over 500 small vials (or 210 large vials), the 600 SLe can process samples at a rate which will satisfy even the most demanding production schedule.



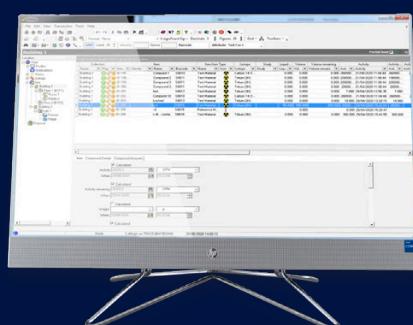
## Hidex 600 OX Sample Oxidizer

The Hidex 600 OX Oxidizer is a fully computer controlled automated catalytic combustion unit for the preparation of samples such as soil, concrete, faeces, tissue, cellulose, paint, adipose, crude oil, blood, plant material, bones, and concrete from decommissioned nuclear power plants.



## Stacy

The Stacy sample tracking and radioisotope stock control system has a host of features for tracking the flow of compounds and samples through a facility, or just for keeping a track of where they are stored with a full chain of custody report.



For further information contact

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# Radiolabelled Service Capabilities

## Radiosynthesis

- Complete management of the radiochemistry process
  - Selection of label position in the molecule
  - Optimization of the radiosynthetic pathway and yield
  - Choice of  $^{14}\text{C}$  or  $^3\text{H}$
  - GMP or GLP certification available

## Clinical hAME studies with $^{14}\text{C}$ Compounds

- Absorption, metabolism and excretion for mass balance & PK (AME)
- IV microtracers for absolute bioavailability (ABA)
- AMS (Accelerator Mass Spectrometry)
- High resolution mass spectrometry (HRMS) for MetID
- Bioanalysis and biomarkers (LC-MS/MS, immunoassay)

## Non-clinical ADME & QWBA with Radiolabelled Compounds

- Pharmacokinetics, biliary excretion & excretion balance
- Tissue distribution (QWBA, mARG) and dosimetry
- Metabolite profiling & MetID
- Bioanalytical support (LC-MS/MS)

## Environmental Fate & Metabolism Studies

- Plant and livestock metabolism
- Physical chemistry
- Biodegradation
- Aquatic & terrestrial ecotoxicity
- Laboratory Animal Metabolism
- Dermal Penetration Studies



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Information sheet

## Isotope Labelling

**Whether you need isotopically labelled (14C/SIL) compounds for non-clinical or clinical metabolism studies and the quantification of materials in biological matrices, our expertise provides the necessary labelled materials tailored to support your studies.**

With over 30 years of successful delivery on-site, Quotient Sciences' highly trained chemists have extensive chemical and radiochemical knowledge and the experience required to supply consultancy and advice on the most suitable labelling positions for a variety of molecular entities.

### Trust us to deliver on time in, in full – 98% delivery rate at Quotient

#### What we can do for you

We pride ourselves on accelerating your drug compounds to the clinic. Our team of experts provide guidance on the design and conduct of both non-clinical and clinical human ADME studies for research, development and regulatory purposes. Our radiolabelling expertise is available as a standalone service or as part of our integrated Synthesis-to-Clinic™ offering. Customers who have placed both their non-clinical and clinical studies with us, have shortened their time to clinic and saved on development costs by avoiding the need for re-synthesis.

#### Applications include

- Ability to safely handle high potency/high hazard compounds (cytotoxics)
- Synthesis of metabolites & reference materials aiding bioanalytical and metabolism studies
- Degradants and process impurities to support API development
- Route development and precursor synthesis for labelling with <sup>3</sup>H and short-lived isotopes <sup>11</sup>C and <sup>18</sup>F
- Experienced in classical and non-classical synthetic techniques, microwaves reactors, H/D-cubes, automated peptide synthesis, microbiological and bio-catalysis

#### Why choose Quotient Sciences?

- >30 years successful delivery on-site
- 98% delivery rate with over 200 projects completed
- 14C for non-clinical and clinical studies
- Stable isotope (e.g. <sup>2</sup>H, <sup>13</sup>C, <sup>15</sup>N, <sup>18</sup>O) labelled compounds for mass spectroscopy standards

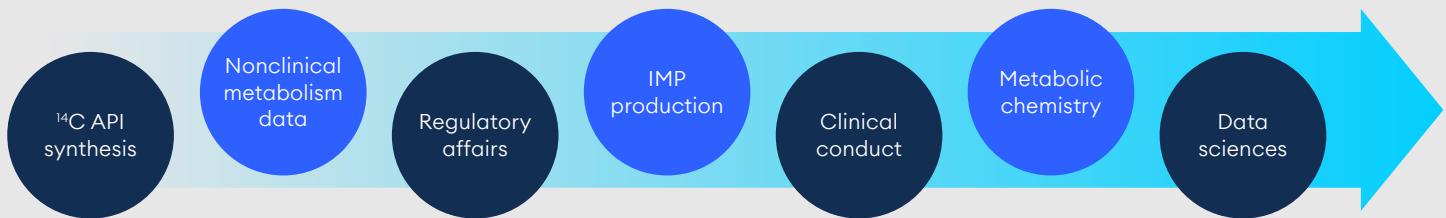
#### Our state-of-the-art equipment includes:

Vacuum manifold equipment for handling volatile <sup>14</sup>C starting materials, HPLC, LC-MS, GC-MS, liquid scintillation counters, radio-TLC imagers and H-Cube flow hydrogenation systems.

## Facilitated by Synthesis-to-Clinic®

Our Synthesis-to-Clinic® support – from radiosynthesis to final clinical report – pulls all the necessary elements required for the completion of a human ADME program together into a single, integrated program of work. It drives efficient development and manufacturing of 14C drug products tailored to the specific requirements of your ADME program – including intravenous (IV) products to generate IV pharmacokinetic and absolute bioavailability data, where appropriate. This platform supports your entire ADME program, from radiosynthesis through to clinical reporting, delivering all of these components on your behalf under the guidance of a single Quotient project manager.

A global network of pharmaceutical sciences facilities for the development, real-time GMP manufacture and QP release of 14C drug products enables us to seamlessly supply oral and parenteral formulation of ADME studies. GMP manufacturing of 14C drug product is conducted in the same building as clinical dosing and real-time adaptive manufacturing allows us to support ADME studies in patients at specialist clinics.



## 14C Radiolabelling

### Why choose Quotient?

We are MHRA accredited and offer full GMP synthesis of 14C-labelled compounds for human studies. We are experts in the safe handling of 14C- high potency / high hazard compounds (cytotoxics) and 14C-labelled gases and volatiles, including 14CO<sub>2</sub>.

We support projects through separate, complete syntheses of non-clinical and clinical batches, or by synthesis of a pre-clinical intermediate, which can subsequently be used to prepare non-clinical and clinical batches. The latter approach can avoid the need for re-synthesis, saving our clients' time and reducing costs associated with providing labelled material for human ADME studies.

### How do we do it?

Our collaborative approach, facilitated by our all-in-one facility, enables us to draw on the multidisciplinary expertise of a strong analytical and drug product team, delivering a service that helps our customers through all stages of the drug development process. With formulation development, IMP manufacture and dossier writing expertise on-site, we provide greater flexibility for integrating the provision of labelled materials with your development program.

### Stable isotope labelling

We provide synthesis of stable-labelled compounds incorporating <sup>2</sup>H, <sup>13</sup>H, <sup>15</sup>N or <sup>18</sup>O and have the ability to perform H/D exchange on API or late stage intermediates. The use of stable labelled standards is recommended by EMA (guideline on bioanalytical method validation), AAPS/FDA (BMV Conference Report) and endorsed by the European Bioanalytical Forum and Global Bioanalytical Consortium. Our team has supported numerous bioanalysis studies for a diverse range of molecules and we have the experience required to ensure project success.



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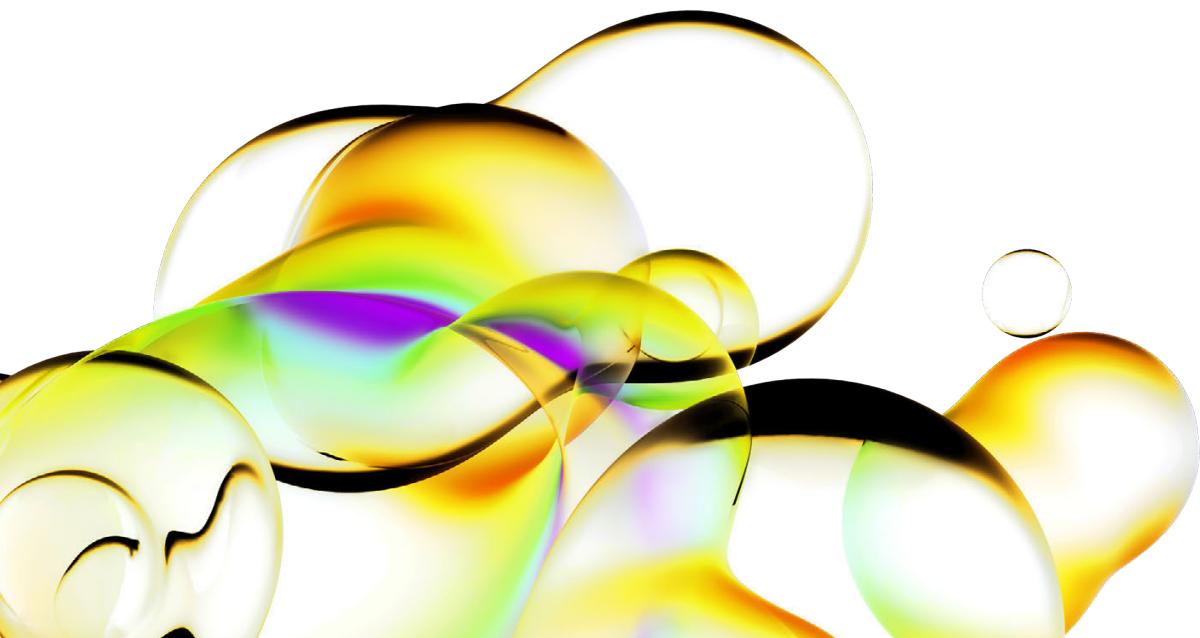
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