

The IATDMCT COMPASS

News and Views on TDM and CT from around the World

IATDMCT 2009 ELECTION RESULTS

Anyone with a computer probably knows the outcome of our recent election. However, The Compass wishes to acknowledge the Association members who are willing to stand for office and who will begin their terms at the 2009 Congress in October by announcing the results in print. So, congratulations to:

- Dr. Alexander Vinks (USA), President
- Dr. Pierre Marquet (France), former Secretary, now President-Elect
- Dr. Hans Maurer (Germany), former President, now Past President
- Dr. Donald LeGatt (Canada), former Director of Education, now Secretary
- Dr. Loralie Langman (USA), former Councillor, now Treasurer

- Dr. Vanessa Steenkamp (South Africa), new Director of Education
- Dr. Tuen van Gelder (Netherlands), former Councillor, now Director of Education
- Dr. Pierre Wallemacq (Belgium), former Councillor, now Director of Education

- Drs. William Clarke (USA), Mercé Brunet (Spain), Frank Peters (Germany) and Benedetta Salustio (Australia), all new Councillors

And thank you to our outgoing officers:

- Dr. David Holt (UK), former Past President
- Dr. Victor Armstrong (Germany), former Treasurer
- Drs. Marilyn Huestis (USA), Atholl Johnston (UK), Sondra Solari (Chile), all former Directors of Education
- Dr. Christine Collier (Canada), former Councillor

IATDMCT DIRECTORS OF EDUCATION FORM TASK FORCE, DEVELOP FUNDED INITIATIVES

by Alexander Vinks, IATDMCT President-Elect

With the acquisition by IATDMCT of the journal Therapeutic Drug Monitoring our Association has become financially more independent. This has opened the door for IATDMCT to increase support to standing programs, as well as to develop new initiatives to increase educational support and programs, and international TDM awareness and membership. For this purpose the Executive last year installed a special Task Force for Standing Programs. Members are Prof. Dr. Alexander A. Vinks, President-Elect, Directors of Education Dr. M. Huestis (Baltimore, MD, USA), Prof. Dr. A. Johnston (London, UK), Prof. S. Solari (Santiago, Chile), and Elizabeth Hooper (IATDMCT office). The Task Force's mandate is to develop a structure for standing programs such as the Traveling Lectureship, Congress Travel Grants, and longer term educational goals of the society that are offered annually.

The Task Force has had an energetic start and met several times by conference call over the past months. Several of its recommendations have recently been approved by the Executive.

Traveling Lectureship: A Traveling Lectureship will be held annually. South America was selected as the next focus area. The 2009 Lectureship will take place in Chile with Dr. Solari as the local organizer. Three cities were selected: Santiago, Antofagasta (metals), and Talca (pesticides). The lectureship will be spread over one week in the period July-August 2009. The topics will be environmental and clinical toxicology. The lectureship format will be a 3-hour lecture and will feature a variety of environmental issues pertinent to South America, including metals and pesticides.

Regional Meetings: IATDMCT will



S. Solari



M. Huestis



A. Johnston

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CLINICAL PHARMACOKINETICS: BASIC GUIDELINE

*An original work of the Clinical Pharmacokinetics
Subcommittee
of the Association of Hospital Pharmacists of Argentina*

The Association of Hospital Pharmacists of Argentina has developed a basic guideline on clinical pharmacokinetics intending to improve the quality of health care to patients. The guideline defines a health center-based Clinical Pharmacokinetic Unit, ideally under the direction of a pharmacist, that will be responsible for ten critical areas with regard to selection and management of therapeutic drugs. These include selection of drugs, selection of patients, selection of analytical methods, interpretation of plasma drug levels, maintenance of records, access to monitoring guidelines, establishment of a quality control system, monitoring quality indicators, development of teaching activities and proposing incentives for conducting scientific studies.

The guideline, developed under the coordination of Dr. Paulo Arturo Caceres Guido, was published originally in Spanish and is available at (http://www.aafhospitalaria.org.ar/norma_farmacocinetica.doc). The English version, translated by Dr. Caceres Guido and edited for English usage by Kimberly Napoli is also available on the IATDMCT website in the Members' Only area under the "Links" tab. For more information or for questions, Dr. Caceres Guido may be contacted by email (caceresguido@gmail.com).

Clinical Pharmacokinetics: Basic Guideline

This document is an original work of the Clinical Pharmacokinetics Subcommittee of the Association of Hospital Pharmacists of Argentina. It represents the opinion on this topic of the Clinical Pharmacokinetics Subcommittee (CPkS) of the Association of Hospital Pharmacists of Argentina (AHPA in English, AAFH in Spanish).

Committee members:

Paulo Arturo Cáceres Guido, Coordinator

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Publication date:

13 November 2008 (Spanish), June 2009 (English)

Drug concentrations in biological samples (usually plasma, but also serum, whole blood, semen, saliva, cerebrospinal fluid or others) are used to estimate the pharmacokinetic parameters of the drug for the patient. Even if the concentration of the drug in the biological matrix versus time is the base to calculate dosage schemes, we also must consider other factors such as the physiopathological condition of the patient, the demographics and the clinical and biochemical parameters.

Drug concentration determinations (therapeutic monitoring) in biological fluids (usually plasma, serum or blood, but also cerebrospinal fluid, semen, saliva, sputum or others) are used to estimate pharmacokinetic parameters in a patient. Those concentrations will be the basis for the calculation of dosage schemes, but those parameters

will not be the only ones. Relevant pharmacotherapeutic, physiopathological, clinical and biochemistry parameters will be considered too.

Clinical Pharmacokinetics (CPk) is a proceeding that contributes to improvement of the quality of health care to patients; in particular, improvement of pharmacotherapy and thus an increase in the probability of reaching therapeutic benefit while minimizing the occurrence of side effects.

A Clinical Pharmacokinetic Unit (CPkU) is defined as an independent and distinct unit. The unit is under the direction of an adequately qualified health care professional, preferably a pharmacist. A pharmacist that is specialized in Clinical Pharmacokinetics, who is mostly known as a Pharmacokineticist, optimizes the pharmacological treatment of each particular patient through principles and study methodologies of Pharmacokinetics.

The CPkU will be a part of the Pharmacy Unit, exclusively, or part of the Laboratory. The responsible party of the CPkU will be a health care professional with known and recognized experience in Clinical Pharmacology. Also the head of the CPkU should have training and experience in clinical areas, and with available time (full or partial) to devote, depending on characteristics of the Unit.

The CPkU must have its own physical space. The Unit will have the necessary analytical equipment, informatics support and sufficient personnel to carry out its activities.

The characteristics of the CPkU can vary between health centers, but its main responsibilities should be:

1) **The selection of the drugs that will be included in the monitoring program.** Any drug that is considered for monitored will be chosen based on a narrow therapeutic range, preexisting data which link concentration and effect, knowledge of factors that can change the PK parameters of the drug, and a wide intra- and inter-individual variability.

2) **The selection of patients who will benefit from pharmacokinetic monitoring.** Each center will determine which patients will be included in monitoring on the basis of the characteristics of each patient. The CPkU can intervene automatically in identifying its own patients using its own logistics or through a consult of a Unit of the hospital. Some patients should be included by necessity, such as neonates, pediatrics, geriatrics, critical care, patients with severe and/or chronic infections, transplant recipients, patients with renal, hepatic or heart failure and patients with a pathology or physiopathological status known to alter the pharmacokinetic parameters of the drug. It is recommended that Therapeutic Drug Monitoring (TDM) be carried out through a request using a written form that will be modified according to the health center and vary, depending on the drug, and the CPkU. The request will include the data necessary to evaluate the clinical state of the patient, demographics, biochemical, and particularly clinical, parameters that the CPkU will define. The physician that participates in the TDM must clearly indicate on the form if the blood samples should be studied as an "Emergency" and, if so, include a telephone number for rapid contact.

3) **The selection of appropriate analytical methods based on the requirements for specificity sensitivity and convenience of validation.** It is recommended that the CPkU have its own laboratory that will carry out analytical quantitation of drugs. The Unit also should coordinate sample collections. The main advantages of this suggested structure are:

a) Direct contact between the Pharmacokineticist and the patient that allows for follow-up of treatment and monitoring for compliance,

b) Suitable programming of sample collection to be insure optimal conditions for the collection (patient already controlled, suspended doses, uncorrected collection of samples),

c) Identification of bioavailability problems, dosing mistakes or unusual PK behavior. At minimum, it is mandatory to know the exact time of the sample collection in order to allow an adequate analysis of the results. Moreover, if the pharmacokinetic analysis requires, the total time for intravenous infusion of a drug should be recorded. The exact time of collection and administration of a drug and the total time of infusion (if appropriate) must be recorded.

4) **The interpretation of plasma drug levels.** Critical factors for interpretation include the characteristics of the monitored drug; the patient's clinical status; renal, hepatic and cardiac functions; the reason for treatment with the monitored drug and concomitant drug treatment. It is advised that a suitable procedure be pre-established so as to ensure that data is accurately collected from of the patient. In any case, the Pharmacokineticist should be able to access the Data Clarification Form.

To calculate individual pharmacokinetics parameters, nonlinear regression and Bayesian methods are recommended. These methods have been demonstrated to be more exact and to have more predictive ability. Computing activities will be done with informatics programs appropriate for each health centre. If needed, consultation with an expert in the field, such as a mathematician specialized in biostatistics/pharmacokinetics, will be made. When the Pharmacokineticist of the CPkU communicates a change in the drug dosage, based on the obtained result with pharmacokinetics analysis, it is recommended notification be made through a formal report called the Pharmacotherapeutic Report or Pharmacokinetic Report (PKR); this report is to be signed and sealed by the head of the unit and the report will be added to the medical history of the patient. The report should include:

a) Date and hour of the redaction of report.

b) New dosage and treatment scheme (in neonates and pediatrics the dosage should be written in milligrams / kilograms or square meter / dose, clarifying frequency).

c) Day and hour when the new posology should be initiated due to potential toxic levels.

d) If and when new controls should be collected.

e) Instructions for contacting the CPkU and their professionals (i.e.; telephone number, e-mail address, etc.) for assistance in clarification of the report.

5) **Maintenance of a permanent record of issued reports and the procedures that were used in monitoring.**

6) **Preparation of pharmacokinetic monitoring guidelines that are distributed to the designated responsible parties in the health center.** Such guidelines may be part of the official pharmacotherapeutic guide of the center which will include the following information:

a) Drugs that are included in the monitoring program and suggestions for their therapeutic ranges,

b) The designations for optimal sampling times,

c) The conditions under which the samples should be obtained,

d) Any susceptible populations that should receive follow up,

e) The suitable analytical techniques depending on the case,

f) The design of the data collection form,

g) The type of report that will be delivered by CPkU,

h) The hours of operation of the CpkU,

i) The hours when samples results and reports will be generated.

The CPkU can also recommend a list of review papers and books that can be used as references. If applicable, guidelines written especially for particular patients will be developed, in particular for ambulatory patients who are taking drugs that are of interest for the CPkU, through consensus with healthcare professionals (i.e.; physicians and nurses).

7) **Establishment of a quality control system for the analytical procedures. In the particular case of the drug concentration quantitation, the controls will be both internal and external.** A system of quality assurance of the activities of the CPkU, which may identify any problems related with the pharmacokinetic monitoring, will be implemented. These controls are intended to find suitable solutions for improving the performance of the CPkU. Part of this quality control system will have to do with services that directly or indirectly tend to optimize the pharmacokinetic analysis system itself, such as a pharmacovigilance unit, drug information or mixing unit, or other.

8) **Proposing incentives for conducting epidemiological studies, cost effectiveness and pharmacokinetic studies, and retrospective and prospective research about clinical pharmacokinetics.** Also with assays associated with pharmacogenetics, studies of possible links between pharmacokinetic – pharmacogenetic – pharmacodynamic parameters (markers) should be conducted. The Pharmacokineticist should join healthcare-associated working groups and/or where contributions to pharmacological research provide clinical relevance.

9) **Monitoring quality indicators of the activities of a CPkU.** Four indicators must be followed:

a) Coverage of monitoring and/or pharmacokinetic monitoring of patients or population groups.

b) Validation of internal and/or external of determinations of concentrations in biological samples.

c) Acceptance of the proposals of the CPkU, in particular the Pharmacotherapeutics Reports.

d) Quantification of participation in educational and research activities.

10) **Development of teaching activities, both within and outside of the health center in terms of agreements with renowned academic medical centers in the country or abroad.** Training of residents, fellows and interns rotating (of our or another country) will be considered a high priority. Other health professionals, especially physicians and nurses, may be accepted or will be convened as special assistant students in related educational activities. In this sense, training of professional Pharmacokineticists, whose business may be properly certified by a National Committee of Clinical Pharmacokinetics, is encouraged.

ORAL FLUID – A SUITABLE MATRIX FOR PROFICIENCY TESTING?

by Matthew Gist

Young Scientists Scientific Issues Series

Advantages of oral fluid as a drug testing matrix

Interest in using oral fluid as the matrix for undertaking screening for drug use has expanded significantly over recent years. There are some good reasons in support of this expansion. The ability to supervise collection without causing embarrassment significantly reduces the chances of the sample being tampered with by the subject. Oral fluid testing is particularly well adapted to roadside testing, providing a sample for immediate analysis. When combined with, for example, the new Cozart® DDS system that boasts a turnaround time of just ninety seconds for two classes of drug and five minutes for six separate classes¹, it can provide data sufficient to initiate law enforcement procedures that will include confirmatory drug analyses. The drug levels found in oral fluid relate to blood levels and correlate well with^{12,14,16}, although they don't necessarily indicate actual extent of impairment. The use of oral fluid in roadside testing has been trialled by various governments in recent years. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines) and ROSITA (Roadside Testing Assessment) programs have conducted field trials of various collection devices and review a large amount of data on their websites (<http://www.rosita.org> and <http://www.druid-project.eu>).

Disadvantages of oral fluid - pH

Oral fluid is not without problems as a matrix for drug analysis. Collection of blood and urine samples is, as a rule, not affected by the method used. Blood collection does not have to be stimulated, a simple needle prick will do. Urine will always come to those who wait. Stimulated collection of saliva actively changes the composition of the oral fluid collected and affects the pH. As a result, the distribution of drugs across the blood / oral fluid interface is altered^{3,17}. Indeed even physiological variability of oral fluid pH can have a considerable influence on these ratios. For example, when codeine was administered to a subject, the levels in oral fluid collected after stimulation with a lemon drop in the mouth decreased by an average of 3.6 times compared to the non-stimulated control sample collected by having

Table 1: Oral Fluid / Saliva Collection Devices²⁰

Collection Device	Company	Method of collection	Control of saliva volume	Buffer / diluent	Stimulated Collection	POCT capability
Cozart® oral swab	Cozart, Abingdon, Oxfordshire. UK	Absorbent swab	Yes	Yes	No	Yes, with Rapiscan or DDS device.
Intercept® device	Orasure, Bethlehem, PA. USA	Salt impregnated pad	No	Yes	Yes	No
Drugwipe	SecureTec, Brunthall, Germany	Absorbent pad	Yes	No	No	Yes
Greiner Bio-One	Greiner Bio-One GmbH, Kremsmünster, Austria	Saliva extraction solution (mouth rinse)	Yes	Yes	No	No
Saliva Twist Device Drug Test	Surescreen Diagnostics, Derby. UK	Sponge swab	No	Yes	No	Yes
Oralab 6	Varian, Palo Alto, CA. USA	Absorbent pad	Yes	No	No	No
Oraline	Sun Biomedical Laboratories, Blackwood, NJ. USA	Collection cup	Yes	No	No	Yes
OralStat	American Biomedica Corporation, Kinderhook, NY. USA	Sponge swab	No	Yes	No	Yes
Oratect	Branan Medical Corporation, Irvine, CA. USA	Absorbent pad	Yes	No	No	Yes
VerOFy	Oasis Diagnostics, Vancouver, WA. USA	Absorbent pad	Yes	No	No	Yes
SalivaScreen	Ulti med products GmbH, Ahrensburg, Germany	Absorbent pad.	Yes	Yes	Yes, acidic available & mechanical	Yes
Smartclip Multidrug	EnviteC-Wismar GmbH, Wismar, Germany	Absorbent pad	No	Yes	Yes, mechanical	Yes
Quantisal	Immunoanalysis, Pomona, CA. USA	Absorbent pad	Yes	Yes	No	No
Salivette	Sarstedt, Nümbrecht, Germany	Cotton wool or polyester swab	No	No	Yes, acidic available & mechanical	No

the subjects spit into inert polyethylene tubes².

Problems with collection devices for oral fluid

The majority of collection devices take the form of an inert absorbent pad which is placed into the mouth between the cheek and jaw (Table 1). These collect unstimulated saliva. The Orasure Intercept® device contains salts in the pad which exert osmotic pressure to draw additional fluids into the pad from the interstitial spaces of the cheek. Once saturated, the pad is inserted into a sample vial containing a preservative solution. The vial is then sealed and transported to a laboratory for testing. A key factor with all such devices is how much oral fluid is absorbed during the collection process. If an assumed value is used which proves to be incorrect, all quantities of drug measured in the sample (irrespective of method) are thrown into doubt, making comparison to a given threshold impossible. There are currently two approaches to solving the volume problem. An indicator in the stem of the device that changes colour

when a sufficient volume of oral fluid is taken up and a dye-dilution approach, which allows measurement of the volume collected. Of the devices listed in Table 1, only the Greiner Bio One¹⁵ utilises the dye-dilution approach. All of the other devices that assess volume rely on an indicator.

The material chosen for the construction of the pad is important. Care must be taken to use materials that will not irreversibly adsorb the drugs being sought. The cannabinoids are particularly vulnerable due to their tendency to adhere to different surfaces and materials^{3,4}. The choice of extraction buffer is therefore equally important. A study comparing various collection devices found the general trend for recoveries was cocaine and benzoylecgonine greater than codeine, morphine, methamphetamine, and amphetamine greater than cannabinoids¹¹.

The buffers/preservatives used vary from device to device and they can cause problems with hyphenated MS techniques used to confirm drug levels. There have been complaints of ion suppression and/or enhancement in liquid

chromatography-tandem mass spectrometry instruments and long-term contamination of columns and ion source in gas chromatography – mass spectrometry instruments⁷.

Problems with Point of Collection Testing (POCT) devices

Devices that perform drug testing at the roadside utilise lateral flow immuno-chromatography (the test sample flows along a solid substrate via capillary action).

Depending on the type of assay used, a positive result will be indicated by either the presence or absence of a coloured band in a set position in a viewing window of the device. Reading these devices in poor light/weather conditions can be problematic and electronic readers are becoming more prevalent. These devices include a control line to monitor correct movement of fluid through the device.

Sample Transport

Any positive result produced by a point of collection device immunoassay must be confirmed by a technique capable of unambiguously identifying individual compounds, typically performed in a laboratory some distance away. The transport delay introduces the possibility of sample degradation that will cause inaccuracies. Stability studies of drugs in oral fluid plus preserving buffer have been conducted for two of the kits currently available. ORALVEQ¹⁸, an EQA scheme for oral fluid, organised by the Institut Municipal d'Investigacio Medica, Barcelona, Spain and

the Department of Therapeutic Research and Medicines Evaluation of the Istituto Superiore di Sanita, Rome, Italy prepared two different samples using the Cozart® drug detection system and Intercept® oral fluid collection devices. In a sample including spiked 6-monoacetyl morphine (6-MAM) and cocaine, the study⁵ found that, for the Cozart® and Intercept® devices, respectively, 11.8 % and 8.8% of the 6-MAM had degraded to morphine and 40.8 % and 26.2% cocaine had hydrolysed to benzoylecgonine. In a separate study of drug stability in spiked oral fluid (carried out by the same institutions) it was found that the addition of citrate buffer (pH 4) and sodium azide (0.1 %) prevented this type of degradation for up to 7 days at 25°C and 37°C, and up to 2 months at 4°C and -20°C⁶.

The role of External Quality Assessment (EQA)

There is a clear need for EQA of drug detection and measurement in oral fluid as a result of the diversity of technologies in use. This need has grown in recent years with routine testing becoming ever more prevalent at the roadside, during pre-employment screening or post-incident at work. Indeed, the framework of international quality standards for analytical laboratories requires involvement in such a scheme⁸ with assessment of laboratory performance through EQA being an important element of a complete quality system^{9,13,20}.

One such scheme was commissioned by Altrix Healthcare (subsequently merged

into the Concateno group) and run by Cardiff Bioanalytical Services Ltd¹⁰. This scheme was offered to laboratories in the Altrix group using the Intercept® oral fluid collection device (Orasure Technologies, Inc., Bethlehem, PA, USA) followed by analysis using an immunoassay technique from the same organisation. The scheme uncovered a lack of sensitivity as the major source of error where the immunoassays failed to achieve their specified cut-offs.

The variety of available collection devices (see Table 1) poses a problem when it comes to designing a more general EQA scheme for oral fluid analyses. The drugs found in a sample are not purely dependent on what drugs are in the subject's system. When an assay fails to detect a drug that is present (i.e., returns a false negative result) is that the failure of the assay or of the collection device? This issue can be addressed by EQA. In the first of two UKNEQAS (United Kingdom External Quality Assessment Service) pilot surveys performed by Cardiff Bioanalytical Services in an attempt to gauge the needs of would-be participants in an oral fluid EQA scheme, the issue of recovery of drugs from collection devices was investigated. Comparison of results for non-extracted samples with those from samples extracted by the laboratory using Cozart oral swab, Greiner Bio-One, Intercept, OraLab6, Quantisal, Salivette and Statsure collection devices showed no significant loss of performance in detection rate nor in quantitative measurements for delta-9-tetrahydrocannabinol (130% recovery), cocaine metabolite (103%), 6-MAM (112%) and morphine (87%). There thus appeared to be no great issue with current collection devices (Note: the over recovery of delta-9-tetrahydrocannabinol was probably an artefact of the losses incurred during laboratory preparation of the more dilute non-extracted sample).

A second issue that is well addressed by EQA schemes is analytical performance. This is gauged as true positive or true negative results versus a defined cut-off. To date, no internationally recognised set of cut-offs have been defined. SAMSHA (Substance Abuse and Mental Health Services Administration) has draft suggestions out for consultation¹³ and the DRUID/ROSITA programs worked to their own defined levels. The SAMSHA guidelines are applicable to workplace drug testing and some regard these cut-offs a little high for drug driving. The UKNEQAS pilot surveys involving 21 laboratories in the clinical, workplace testing, forensic, research and horse racing sectors have identified the following

Table 2: Thresholds to be adopted by the UKNEQAS for Drugs in Oral Fluid

Screening Tests	µg/L	Single Analytes	µg/L
Amfetamine group	35	Amfetamine Methyl-amfetamine MDMA / MDA / MDEA	20 15 15
Barbiturate group	50	Specific barbiturate	5
Cannabinoid group	4	Delta-9-THC	1
Cocaine metabolites	20	Cocaine Benzoylecgonine	5 6
Benzodiazepine group	15	Specific benzodiazepine	3
Methadone or metabolites	25	Methadone EDDP	9 12
Propoxyphene or metabolites	22.5	Propoxyphene or metabolite	35
Opiate group	40	Morphine 6-monoacetylmorphine Codeine Dihydrocodeine	12.5 4 15 10
Buprenorphine or metabolites	1	Buprenorphine or metabolites	1
Phencyclidine	6	Phencyclidine	7.5
LSD or metabolites	0.6	LSD or metabolites	1

Oral Fluids... cont. page 12



**11th International
Congress of
Therapeutic Drug Monitoring
& Clinical Toxicology**

**Montréal, Québec, Canada
Saturday October 3 to
Thursday October 8, 2009**



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PLENARY SESSIONS

- The Role of New Analytical Technologies and Diagnostics in Driving the Future of Medicine
- Better Biomarkers of Acute and Chronic Allograft Rejection
- Neonatal Clinical Pharmacology: Linking Ontogeny, Genetics and TDM in the Most Vulnerable Patients
- Understanding the Regulation of Drug Transport in Disease States and its Impact on Drug Response and Kinetics
- Hot Topics in Drugs of Abuse
- What is Next in TDM and Toxicology

SYMPOSIA

- Is There a Future for Molecular Marker Strategies in Drug Development and Management of Drug Therapy?
- Therapeutic Drug Monitoring During Pregnancy and Lactation; Treating the Mother-Protecting the Baby
- Predictive Value of Pharmacogenomics in the Management of Patients
- Paediatric TDM, They Aren't Just Small Adults
- New Insight Into the Inter-individual Variability of Pharmacokinetics/toxicokinetics
- Emerging Drugs of Abuse
- Advances in Hyphenated Mass Spectrometry Relevant to Clinical and Forensic Toxicology
- Towards Improving the Design and Feasibility of Therapeutic Drug Monitoring Clinical Trials

WORKSHOPS

- Practical LC-MS/MS for Clinical Drug Analysis
- What Would a Benchmark TDM Service Look Like?- Models of Service Delivery
- Methods Development for Quantitative HPLC-Tandem Mass Spectrometry
- Monitoring the Clinical Toxicology Aspects of the Complementary and Alternative Medicine
- Practical Aspects of Oral Fluid On-site Tests for DOA
- Young Scientist Workshop
- Pitfalls in Workplace Drug Testing: Diluted Urine, Use of Adulterants and Drugs Not Included in Test Panels
- Managing Epilepsy Therapy with the Help of Measured Drug Levels: Critical Issues, Case Examples and Third Generation Drugs
- Applications of Pharmacogenetics for Personalized Pain Management
- Biomarkers for Pharmacodynamic Monitoring of Immunosuppressive Therapy - Analytical Aspects
- Antifungal Drugs TDM : An Update



- Monitoring Therapeutic Immunosuppressive, Cytokines and Chemokines
- Personalized Medicine, How Pharmacokinetic and Pharmacodynamic Models are Made and Can Aid Daily Practice to Personalize Drug Treatment
- Alternative Sampling Methods in TDM: Dried Blood Spot and Fingerprick Sampling and Sampling by Reverse Iontophoresis
- Pharmacogenomics of Addiction and Drugs of Abuse
- What are the Differences Between Clinical and Forensic Toxicology? How are we Dealing with Both?
- Pharmacodynamic Biomarkers

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- How Much Sample Preparation for LC-MS(/MS)?
- Pharmacogenetic Variability in Children
- Clinical Tools to Optimize TDM and Individualized Dosage Regimens
- Clinical Utility of Monitoring Free Drug Concentrations
- Bisphenol A (BPA) - The Latest Toxicity Studies and Government Actions
- OTC Medicines - The Need for Public Health Awareness Campaigning as a Monitoring and Evaluation Tool for Iatrogenic Outcomes
- Ethyl Glucuronide in Hair - What is the Best Cutoff to Discriminate Heavy Alcohol Drinkers?
- Roundtable R304: MS Detection Techniques in TDM/ Toxicology - Guidance Documents on Identification Criteria
- Cocaine - Do You Know What You Are Snorting?
- GC/MS - Automated Evaluation of Data Files
- Dermatotoxicity- Clinical and Laboratory Monitoring of Steven-Johnson Syndrome
- The Preanalytical Phase of the Test Cycle in TDM
- Diagnostic Pathways in Clinical Toxicology

- Dried Blood Spot Sampling and TDM of Immunosuppressant Drugs
- Pharmacogenomics for Personalized Justice and Personalized Medicine
- HCV RNA Monitoring in Patients Undergoing Antiviral Therapy
- LC-MS-TOF in Clinical Toxicology
- GHB, GBL, 1,4-BD, GVL, GHV Overview
- Preanalytic Aspects: An Underestimated Cause of Errors in a TDM/TOX Laboratory
- Therapeutic Drug Monitoring of Clozapine and Other Antipsychotics

PRE-CONGRESS SYMPOSIUM

Personalized Immunosuppressive Therapy

- Translational molecular markers will define the future of transplantation: from cage to clinic
- Biomarkers
- Clinical impact of pharmacogenetics
- Clinical transplantation and large trials
- What's new from Pharmaceutical industries



POST-CONGRESS WORKSHOP

Pharmacometric Tools for Maximally Precise Individualized Drug Therapy: Population PK/PD Modelling, Four types of Bayesian Adaptive Control, and Active "Dual" Control

Early Registration Deadline: July 31, 2009

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IATDMCT SYMPOSIUM AT THE 2009 WORLD CONGRESS OF PATHOLOGY AND MEDICINE, SYDNEY

ADVANCES IN THERAPEUTIC DRUG MONITORING

During the 25th World Congress of Pathology and Laboratory Medicine, organized by RCPA and WASPaLM, from 13-15 March 2009 in Sydney, IATDMCT sponsored a Symposium entitled Advances in Therapeutic Drug Monitoring. The Symposium was held on Saturday March 14th in the wonderful congress centre at Darling Harbour. Australian and prominent IATDMCT member Dr. Ray Morris from Adelaide chaired the Symposium.

The first speaker at the Symposium was Prof Michael Oellerich, from Göttingen in Germany, and he spoke about the impact of pharmacogenetics on Therapeutic Drug Monitoring. In his presentation he discussed how genetic variability can lead to inter-individual differences in drug absorption, drug metabolism and drug receptor interactions. As an example, studies were shown on variability in the expression of p-glycoprotein, due to polymorphisms in the ABCB1 (MDR1) genotype. Despite a solid theoretical basis Prof Oellerich showed nicely that for ABCB1 there is a lack of evidence supporting a clear association between gene polymorphisms and clinical drug response or toxicity. For other genes, such as VKORC1 and CYP2C9 (warfarin), UGT1A1 (irinotecan), CYP2D6 (antidepressive drugs, tamoxifen), TPMT (mercaptopurines) and HLA-B *5701 (abacavir) studies have found much stronger clinical relevance. Where so far mostly single-gene studies have been carried out we now see genome-wide pharmacogenomic approaches being undertaken in the analysis of drug-related phenotypes. Prof Oellerich discussed the advantages and disadvantages of these different types of studies and how such studies may lead to what is now called "personalized medicine".

Dr Teun van Gelder from Rotterdam, in The Netherlands, gave an overview of the possible methodologies for monitoring immunosuppressive drug therapy. Within the field of solid organ transplantation there is an unprecedented interest in therapeutic drug monitoring of immunosuppressive drugs, not only for recently introduced drugs, but also for established agents such as azathioprine and cyclosporine. Pharmacokinetic monitoring



Prof. Holt, Oellerich, van Gelder and Morris following their symposium at the World Congress on Pathology & Medicine.

usually focuses on reaching certain target drug concentrations. Such ranges have been developed by retrospective review of drug concentration data and their correlation with clinical outcome. Multicenter concentration-controlled clinical trials can provide a basis for designing future prospective TDM investigations. Ideally, added to these trials also one or more pharmacodynamic tests should be added, to quantify the biological effect of the drugs applied. Although on theoretical grounds monitoring the pharmacodynamic effect makes more sense than monitoring drug concentrations, in daily practice pharmacodynamic monitoring is not performed. Defining optimal ranges for pharmacokinetic and pharmacodynamic drug monitoring of immunosuppressive drugs may lead to further improvement of the safety and efficacy of our immunosuppressive regimens.

The third speaker at the Symposium was Prof David Holt from London, UK. His presentation focussed on documenting assay quality in TDM. Laboratories should strive for consistency of bioanalytics, using a validated method, demonstrating calibrator accuracy with acceptable reproducibility and consistency of results over time. Although most of these points seem obvious, in daily practice there are many reasons for not always achieving these goals. For example, absence of reference methods or absence of certified reference materials may compromise the methods. Prof Holt showed some striking examples of analytical problems from his long experience in the monitoring of immunosuppressive drugs and antiretroviral agents. Clearly the need for proficiency testing, including with patient-derived samples, is high and with the availability of more diverse methods this is increasingly important.

The speakers are grateful to IATDMCT for the travel grant that allowed them to make the trip "Down Under" and to present at this wonderful symposium, at which there was a lively and attentive audience.

Personal
PROFESSIONAL
Big events in the lives of IATDMCT Members



Christoph Sauer, successfully defended his thesis entitled "*Phencyclidine Derivatives – A New Class of Designer Drugs; Studies on the Metabolism and Toxicological Analysis,*" on 18 December 2008. His promoter is Prof Hans H. Maurer, President of IATDMCT and Head of the Department of Experimental and Clinical Toxicology, Institute of Experimental and Clinical Pharmacology and Toxicology, Saarland University. Christoph is now a scientific coworker at the Institute of Forensic Medicine, Friedrich Schiller University, Jena, Germany, where he is a supervisor in Clinical Toxicology and covers aspects of forensic toxicology. Congratulations Christoph!



During the congress banquet, the Director of the Dubai Health Authority, Dr. Qadhi Saeed Al Murooshid (left), and Dr. Ali Al Sayed presented a special gift to Hans Maurer.

IATDMCT PRESIDENT HONORED

The DUPHAT, Dubai International Pharmaceuticals and Technologies Conference and Exhibition, took place this year from March 29-31. It was organized again under the auspices of IATDMCT by Dr. Ali Al Sayed, Director of Pharmaceutical Services Department, at the Dubai Health Authority. Speakers from all parts of the world reported this year mainly about clinical pharmacy to more than 2000 participants from various Arabic countries. IATDMCT President Hans Maurer was invited to give a plenary lecture about Toxicokinetics of Drugs of Abuse. At the end of his presentation, he promoted IATDMCT and particularly the Montreal Congress in October.

The abstract for Dr. Maurer's lecture:

Toxicokinetics of Drugs of Abuse: Relevance for Predicting Pharmacogenetic Variations, Interactions, or Pitfalls in Drug Testing

Individual variations in the pharmacological responses to the same drug dose may be caused by a variety of factors such as body mass, age, sex, kidney and liver function, drug-drug (food-drug) interactions, or genetic variability [1]. Detailed knowledge of the metabolism of drugs allows to predict possible interactions with other xenobiotics because of e.g. inhibition or induction of individual metabolic isoenzymes by poisons, drugs (of abuse), alcohol, or ingredients of tobacco or food [2-4]. Hence, understanding pharmaco-/toxicokinetics and pharmacogenetic variations is a prerequisite for evidence-based case interpretation, for toxicological risk assessment, for developing toxicological analysis procedures, and for understanding pitfalls in drug testing. In the presentation, the major metabolic pathways and the involved isoenzymes in humans will be summarized for the major drugs of abuse. It will also provide an overview on the implications of the presented data for possible interactions of drugs of abuse with other xenobiotics, i.e. inhibition or induction of individual polymorphic and non-polymorphic isoenzymes.

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Welcome new IATDMCT members Victoria Bull, Julie de Smet and Hylke de Jonge!

Victoria Bull, graduated in June 2007 with a BSc in Biochemistry and Pharmacology from the University of Surrey, UK. Since December 2007, Victoria has worked as an Analytical Biochemist in Prof David Holt's group at the Analytical Unit, St. George's University of London. Victoria is training in the development of analytical methods, LC-MS(/MS), HPLC/UV and GC/MS, for the detection of a variety of endogenous compounds, drugs and their metabolites, for both routine and research analyses. She has also been involved in the implementation of a routine antiretroviral TDM service at St George's. Her main reasons for joining IATDMCT are to use the Association as a networking opportunity to learn from established members and also her peers. She wishes also to become an active Young Scientist member. This year Victoria is running in the "Race for Life" in aid of cancer research. This is in memory of her partner's granddad, who passed away from lung cancer. Victoria is also getting married in July 2010, so planning is taking up most of her spare time!



Julie De Smet, lives in Belgium and is already a Young Scientist committee member. Julie graduated as a Pharmacist from Ghent University in 2006. Subsequently, she started her PhD entitled "Bio-analysis and Pharmacokinetics of Fluoroquinolones and Proton Pump Inhibitors" at the Laboratory of Medical Biochemistry and Clinical Analysis (Faculty of Pharmaceutical sciences, Ghent University). Julie's research interests are in the influence of pathology on the pharmacokinetics of three fluoroquinolones (ofloxacin, ciprofloxacin and moxifloxacin) in critically ill patients. Consequently, to enable routine analysis of these three fluoroquinolones, she has developed and validated a bio-analytical method for their simultaneous quantification in human plasma. Julie has also studied the influence of pathology on the pharmacokinetics of omeprazole in patients with cerebral palsy and mental retardation. Patient plasma samples were analyzed using a HILIC-MS/MS method that she also developed and validated. Julie has published her work and has presented at local and international conferences.

Hylke de Jonge, graduated as a Medical Doctor from the Catholic University of Leuven, Belgium, in 2003. After three years of residency in Internal Medicine, he is now combining a doctoral training program in Biomedical Sciences with further clinical training in Internal Medicine and Nephrology. The translational research performed in the framework of his PhD-project is conducted at the Department of Nephrology and Renal Transplantation, University Hospitals Leuven, under supervision of Prof. Dr. D. Kuypers and is funded by a grant of the Research Foundation – Flanders. The department is performing approximately 140 kidney transplantations each year and has been involved in research into immunosuppressive drug pharmacokinetics, pharmacogenetics and TDM in solid organ transplantation for more than a decade. His PhD project mainly focuses on calcineurin inhibitor metabolism and pharmacokinetics in renal allograft recipients and its impact on clinical outcome after kidney transplantation. It combines various approaches to further unravel this intriguing and clinically relevant issue. Preliminary results of the ongoing trials have been presented at the IATDMCT-sponsored ImmunoTDM meeting that took place in Warsaw Poland in September 2008, and at various national and international Nephrology and Transplantation congresses as well. As he enjoyed the ImmunoTDM meeting very much, he decided to join the IATDMCT. Hylke is looking forward to meeting other IATDMCT members interested in TDM of immunosuppressive drugs at the IATDMCT Congress in Montreal.



WELCOME NEW TDM JOURNAL REVIEWS EDITOR, LORALIE LANGMAN

Dr. Offie Soldin, recently resigned as Reviews Editor of the official journal of the Association, Therapeutic Drug Monitoring, after an excellent run. And Dr. Loralie Langman accepted the invitation to fill this position. As well, she was recently elected as IADTMCT Treasurer for the 2009-2011 term.



Dr. Langman is not a stranger to hard work or multitasking! She began her scientific education at the University of Alberta, completing her PhD in Medical Sciences under Dr. Randall Yatscoff (former IADTMCT Young Investigator awardee and President) in the Department of Laboratory Medicine and Pathology in 1996, followed by a post-doctoral position at the University of Toronto. After a few years working in Toronto and British Columbia she became a Senior Associate Consultant for the Mayo Clinic in 2005. This was followed shortly with an appointment as Assistant Professor of Laboratory Medicine & Pathology. Currently she is the Director of Toxicology and Drug Monitoring in the Division of Clinical Biochemistry and Immunology, a Consultant to the Division of Clinical Biochemistry & Immunology at "the Mayo" AND, in April 2009, was appointed as Associate Professor of Laboratory Medicine & Pathology at the Mayo Clinic College of Medicine.

Dr. Langman is board certified as a Medical Laboratory Technologist by the Canadian Society for Medical Laboratory Science and the American Society of Clinical Pathologists. In addition she is board certified in Forensic Toxicology by the American Board of Forensic Toxicology. And she is the first to be triply certified by the American Board of Clinical Chemistry in Clinical Chemistry, Molecular Diagnostics and Toxicological Chemistry! She now holds a place on their Board of Directors.

Numerous presentations have taken her to many destinations across North America and to Italy, Spain, France and the Cayman Islands. She currently has six book chapters in press!

To say Dr. Langman is well versed in TDM and Toxicology is an understatement. This new TDM Reviews Editor knows these topics inside and out! Undoubtedly she will be a real asset to the journal's editorial board. Welcome aboard, Loralie!

ANNOUNCING AN AACC SPONSORED EDUCATIONAL EVENT

**PERSONALIZED MEDICINE IN ONCOLOGY
and the MANAGEMENT of CHEMOTHERAPEUTICS**

September 23-24, 2009

**Sheraton Baltimore City Center
William Clarke, Meeting Chair**

This program for physicians, clinicians and health care researchers in oncology will address the role of TDM and pharmacogenomics in management of chemotherapy, how to overcome obstacles for implementation of personalized oncologic medicine, opportunities for utilizing lab support in optimizing chemotherapeutics, and will address the growing need for multidisciplinary support of personalized oncologic medicine. Hear case-based discussions and regulatory and payer perspectives on personalized medicine.

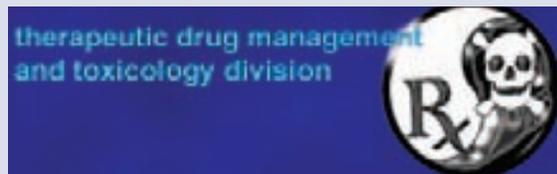
This meeting is designed by the AACC TDM/TOX Division in cooperation with the American Society of Clinical Oncology.

To learn more or to register, visit the website:

<http://www.aacc.org/events/meetings/pages/5205.aspx>

ANNOUNCING! DRUG ADDICTION: FROM BASIC SCIENCE TO CLINICAL LABORATORY PRACTICE

A Symposium of the TDM/TOX Division of AACC



**July 18 (Saturday); 5:30 to 7:30 PM (reception following)
Hyatt Regency Chicago, Crystal Ballroom**

Speakers

Lionel Raymon (University of Miami)
"Neurobiology of Addiction"

Marilyn Huestis (National Institutes of Drug Abuse)
"Pharmacokinetics and Disposition of Drugs of Abuse and Their Impact on the Design of Drug Testing Programs"

Dennis Crouch (Aegis Sciences Corporation)
"Considerations in Oral Fluid Testing: Collection, Analysis and Interpretation"

To register, visit the AACC website.

STANDARDS OF LABORATORY PRACTICE (SLP) COMMITTEE CO-CHAIRS ANNOUNCE MONTREAL WORKSHOP

by Edgar Spencer and Christoph Hiemke

The Standards of Practice Committee invites you to join their workshop “**What Would a Benchmark TDM Service Look Like?-Models of Service Delivery**” to be held at the IADTCMT 2009 Congress in Montreal.

At present there is no recognised benchmark model of service delivery. This workshop will consider the hypothetical and practical elements of a benchmark TDM service and in particular models of service delivery, with opportunity for participant involvement. Profs Norris and Morris will discuss results of a recent survey of TDM in Australia and New Zealand which indicated that the practice of TDM is of variable standard. The three other international speakers, from Canada, South Africa and the UK, will present how TDM is delivered in their institutions. They will consider pre-analytical, analytical and post-analytical aspects of the service, including regional service delivery models and national practices and guidelines.

At the end of the workshop participants will understand how

to evaluate a TDM service against a benchmark with respect to quality of laboratory data and effectiveness of patient management; understand and appreciate the various models of TDM service delivery that are effective and the factors, including funding models, that influence the choice of service model; and understand and appreciate issues related to different models of TDM service delivery for rural and urban services.

The workshop will be chaired by **Ross Norris**, A/Prof., Research Consultant, Australian Centre for Paediatric Pharmacokinetics, Mater Health Services, Raymond Terrace, South Brisbane, Australia and **Raymond Morris**, PhD, Chief Medical Scientist, Clinical Pharmacology, The Queen Elizabeth Hospital, Woodville, South Australia. Affiliate Associate Professor, Discipline of Pharmacology, University of Adelaide, Adelaide, Australia. Other speakers will be **Donald F LeGatt**, PhD, FCACB, Professor & Head, Clinical Toxicology and TDM Laboratory, University of Alberta Hospital, Capital Health, Edmonton, and Consultant Toxicologist, DynaLIFEDx Diagnostic Laboratory Services, Edmonton, Canada; **Vanessa Steenkamp**, PhD, Professor & Head Phytomedicine Unit, Department of Pharmacology, University of Pretoria, South Africa; and **Phillip E Morgan**, PhD CChem MRSC, Deputy Head Toxicology Unit, Department of Clinical Biochemistry, King’s College Hospital, London, UK.

INVITATION TO ALL IATDMCT YOUNG SCIENTISTS FROM THE CHAIR AND SECRETARY!

The IATDMCT Congress in Montreal is rapidly approaching and we are very much looking forward to meeting you all in this great location. Those of you who have already registered have certainly noticed that there is large discount on the registration fee for IATDMCT Young Scientist (YS) members. In fact, the fee for YS members is \$300 (!) lower than for regular members. For those who have not yet registered, the discount is certainly one good argument to do so very soon.

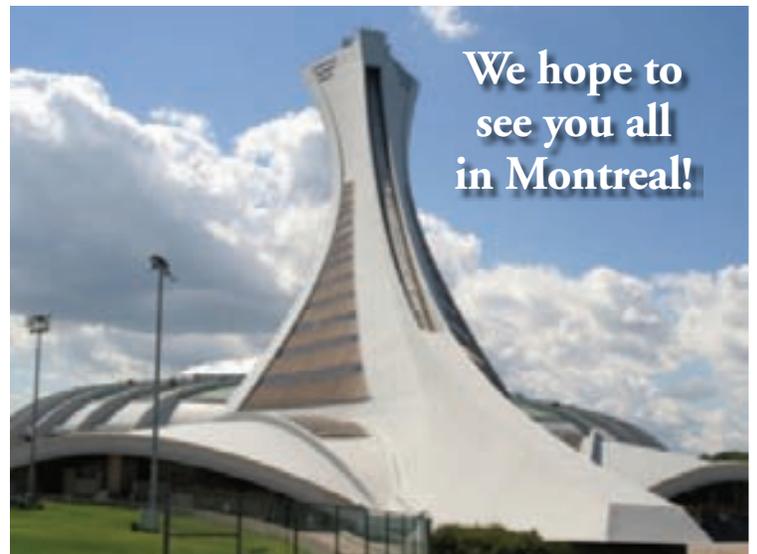
However, this is not the only reason. As in Nice 2007, there will be a YS lunch at the beginning of the Congress; Sunday 4th October. This is a great opportunity to meet and socialize with other YS from all around the world, especially for first-time participants.

Following the lunch, there will be the YS Workshop! This will cover polymorphisms of metabolic enzymes and their clinical relevance, Bayesian statistics in PK modeling and dose adjustments, and new designer drugs. Thus, covering topics from therapeutic drug monitoring and clinical toxicology, and giving all participants an opportunity not only listen to presentations from their own area of research but also learn about important aspects from related fields.

Moreover, we are happy to announce that for the first time there

will be Young Scientist Prizes for the best oral and poster presentation during the meeting. For details, see the IATDMCT website. We hope many of you submitted your work for consideration during the registration process. Finally, YS may have a chance for receiving the new Patsalos Prize (see website for details) and we wish you all good luck and hope your previously published papers may be considered for this prestigious award.

From: Frank T. Peters, Chairman, IATDMCT YS Committee and Denise A. McKeown, Secretary, IATDMCT YS Committee



median values to be in use.

Relative to these median values, the main source of false negative reports in the UKNEQAS surveys derived from under performance by immunoassay products. Four screening laboratories reported buprenorphine as 'not found' in positive samples. The number of false negative reports was amphetamine 22%, benzoylcegonine 10%, nordiazepam 11%, dihydrocodeine 19% and buprenorphine 67%. A further 38% of laboratories missed dihydrocodeine as it fell outside the fixed range of analytes on which they reported.

The third area of strength of EQA surveys is their ability to investigate and illustrate problems in data interpretation and hence provide educational support. There is still unfortunately a need to continually reinforce the mantra that immunoassay positive results need confirmation. This objective will underpin the oral fluid EQA scheme being launched by UKNEQAS in June 2009. The need can be demonstrated by incorrect interpretation of positive group test results produced by common over the counter and prescribed medications. The cross reactivity of codeine with opiate assays is a good instance which has been interpreted as heroin abuse.

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facilitate the organization of regional meeting in the off-year of the Congress, with the first one to take place in China in 2010. A region in a developing area/country will be identified to be the focus for a minimum of 4 years (i.e., 2 meetings, to maximize the opportunity to develop the science in the area). The proposed structure is loosely based on the successful TIAFT regional meeting model. The selected country or region should have sufficient infrastructure through a local organization or university backing. The meeting will be held every second year and IATDMCT will commit financial support for two meetings and then continue to support but not provide funding. The goal is to develop or build a local organization that can organize its own meetings. The meeting should include sponsorship and exhibits, if possible, and local attendees will be provided with an IATDMCT certificate. The local organizers will advise on the appropriate companies to be approached by the Association. IATDMCT will also help by providing prominent speakers (2-3) but there will also be local speakers and/or young scientists (2-3) and an opportunity for the local attendees to present posters. The IATDMCT speakers will speak in English, but the local speakers and posters could be in the language of the region. These two-day meetings will be held in a hospital or university and costs will be kept as low as possible.

Congress Travel Grants: The Task Force has modeled a grant structure on the AACC grant system. A limited number of International Travel Grants will be available to help offset travel expenses to attend the IATDMCT Congress. The following criteria were identified: (1) Open to members from developing countries in good standing, (2) Young Scientists will be identified as those with 10 years or less of experience in the field of TDM or Clinical Toxicology, (3) Candidates must submit an abstract, (4) A letter from a supervisor on letterhead supporting the application and indicating that full funding is not available for the candidate to attend the Congress. The travel grant is described in full detail in the 'Terms of Reference' and is posted at the IATDMCT website (www.iatdmct.org). The goal will be to fund two candidates from developing countries and two Young Scientists, but will depend on the number and quality of applications, as well as available funds. The level of funding support for each Congress will be decided by the Executive.

IATDMCT COMPASS

The *Compass* is published quarterly by the International Association of Therapeutic Drug Monitoring & Clinical Toxicology and distributed to the members by the Association. Letters to the Editor must be signed and should not exceed 200 words in length. Chairs of Committees are requested to submit announcements and reports of activities.

Deadlines for submission:

1st quarter issue	February 15
2nd quarter issue	May 15
3rd quarter issue	August 15
4th quarter issue	November 15

Views and reports appearing in *Compass* do not necessarily have the endorsement of the Association. Address general communications to the Editor care of the IATDMCT Head Office.

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