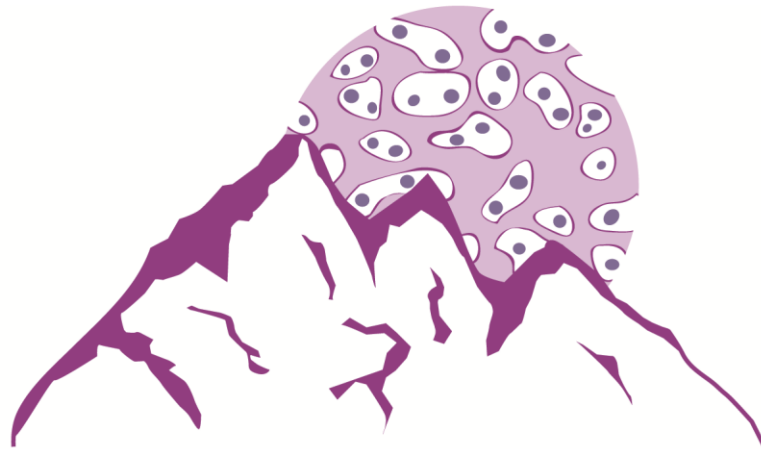


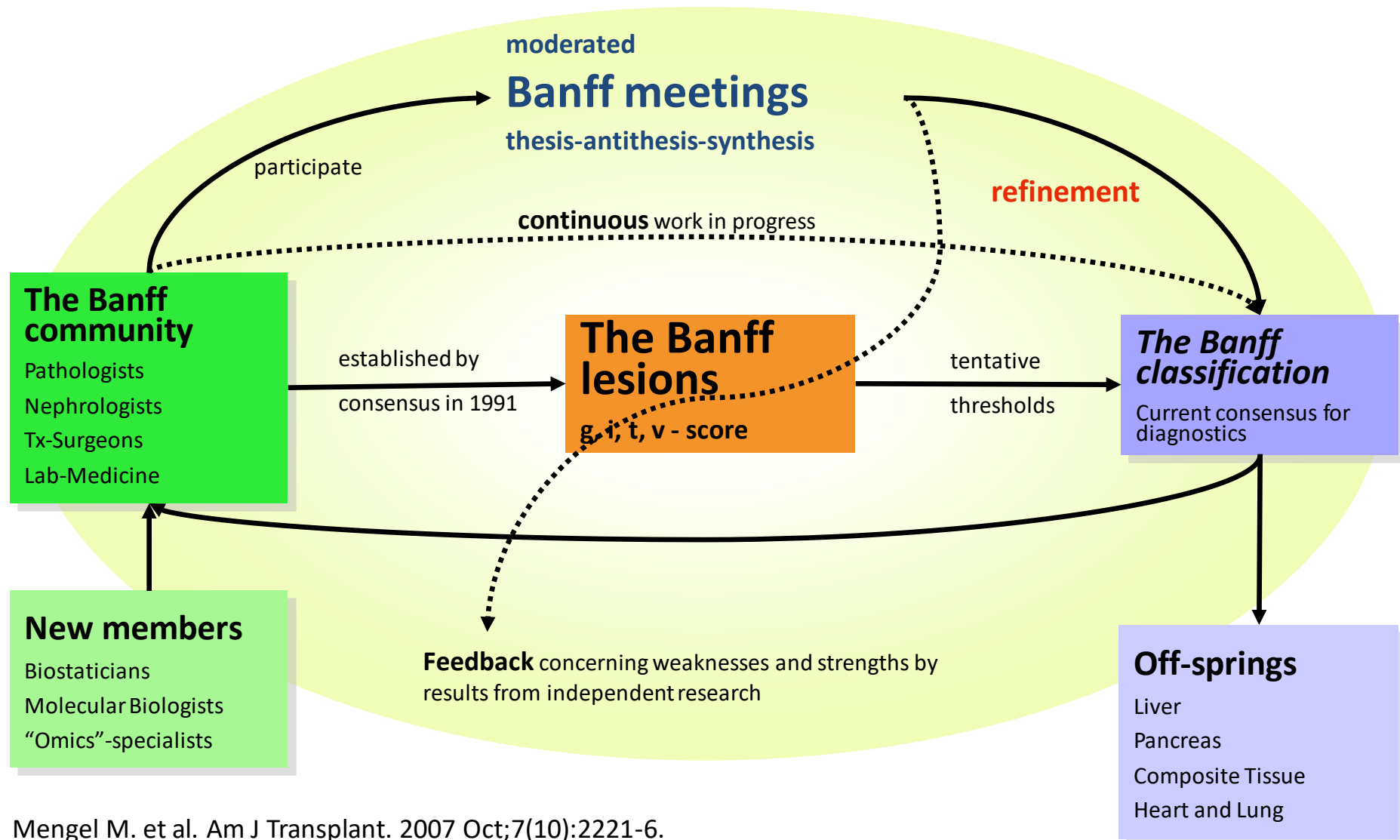
2017 Report form the Banff Foundation For Allograft Pathology



BANFF FOUNDATION
FOR ALLOGRAFT PATHOLOGY

The Banff Process: 1991 - today

A self-organizing consensus system in transplantation



Clinical Relevance and Impact of the Banff Process

History of the Banff classification of allograft pathology as it approaches its 20th year

Kim Solez

Department of Pathology, University of Alberta, Edmonton, Canada

Correspondence to Kim Solez, MD, Department of Pathology, 5B4.02 WCM HSC, University of Alberta, Edmonton, Canada T6G 2R7
Tel: +1 780 407 2607; fax: +1 780 407 2608; e-mail: Kim.Solez@UAlberta.CA

Current Opinion in Organ Transplantation 2010, 15:49–51

Purpose of review
To revisit the history and main defining characteristics of the Banff classification.

Recent findings
From small beginnings in 1991 the Banff classification of renal allograft pathology has grown to be the major standard setting force in renal transplant pathology and in international clinical trials of new antirejection agents. The meeting and classification has unique history, consensus generation mechanisms, funding, and tradition, and looks poised to continue for at least another 20 years. The Banff meetings also deal with

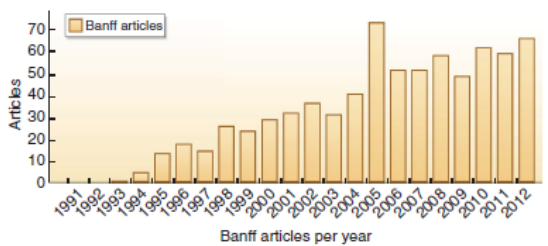


Figure 1 | Number of Banff articles in transplantation per year.
The peak of 73 articles in 2005 was the combined effect of increasing interest in antibody-mediated rejection and viral disease, and the controversy surrounding the term ‘chronic allograft nephropathy’. The distribution into categories was Kidney-Clinical (human) 611, Kidney-Experimental 40, Liver-Clinical (human) 48, Liver-Experimental 8, Pancreas-Clinical (human) 4, All Organs-Clinical (human) 2, Composite Tissue-Clinical (human) 3, and Heart-Clinical (human) 1. There are 38 articles thus far in 2012 to July 31, which extrapolate to 65 for the year making 2012 the second highest year for Banff articles.

Table 1 | Banff Allograft Pathology Meetings since 1991 with key themes

	Location	Length (days)	Links	Key subjects debated
1991	Banff, Canada	1.5	ISN	Classification established, lesion scoring, diagnostic categories, physician-led consensus
1993	Banff, Canada	3	ISN, CAP	Liver classification, chronic rejection, first presentation on molecular pathology approaches
1995	Banff, Canada	4	ISN	Pancreas classification, glomerulitis, first international medical meeting on CD-ROM, first Banff conference with microscope sessions. Lesion scoring normalized with CADI.
1997	Banff, Canada	5	ISN	Merging of Banff and CCTT classifications, establishing basis for current Banff classification, post-transplant lymphoproliferative disorder, first Banff conference with posters
1999	Banff, Canada	5	ISN, NKF, NIH	Protocol biopsies, chronic rejection, and viral diseases, clinical practice guidelines. First conference supported by an NIH grant.
2001	Banff, Canada	5	ISN, NKF	AMR, donor biopsies, genomics, CAN, heart transplantation
2003	Aberdeen, Scotland	4	ISN, NKF	C4d, macrophages, tolerance, accommodation, immunodepletion
2005	Edmonton, Canada	6	NKF	Genomics and molecular markers, B cells, chronic allograft injury with elimination of CAN, establishment of criteria for chronic rejection
2007	La Coruna, Spain	6	UofA	Protocol biopsies, transcriptome, mechanisms of rejection, ptc grading, new total inflammation score; working groups for v-lesion, genomic integration, pancreas and composite tissue rejection schemas
2009	Banff, Canada	5	UofA	Viruses, quality assurance, AMR in kidney, heart, and pancreas, liver allograft accommodation, endothelial cells, surrogate markers. Working groups.
2011	Paris, France	5	UofA	Sensitized patient, C4d, isolated v-lesion, the future, genomics, glomerulitis, epithelial injury/epithelial mesenchymal transformation, operational tolerance monitoring in liver grafts
2013	Comandutuba, Brazil	5	Banff Foundation	Definition of C4d-negative ABMR, adoption of molecular diagnostics
2015	Vancouver, Canada	5	Banff Foundation / CST	Molecular Diagnostics consensus process
2017	Barcelona, Spain	5	Banff Foundation / SCT	New end-points for Next-Generation Clinical Trials, role of i-IFTA

Google Scholar – Citations of Banff reports

- Banff 07 classification of renal allograft pathology: updates and future directions K Solez, RB Colvin, LC Racusen, M Haas, B Sis, M Mengel, PF Halloran, ... American Journal of Transplantation 8 (4), 753-760, 2008 1175
- Banff05 Meeting Report: differential diagnosis of chronic allograft injury and elimination of chronic allograft nephropathy (‘CAN’) K Solez, RB Colvin, LC Racusen, B Sis, PF Halloran, PE Birk, ... American Journal of Transplantation 7 (3), 518-526, 2007 880
- Banff09 meeting report: antibody mediated graft deterioration and implementation of Banff working groups B Sis, M Mengel, M Haas, RB Colvin, PF Halloran, LC Racusen, K Solez, ... American journal of transplantation 10 (3), 464-471, 2010 465
- Banff 2011 Meeting report: new concepts in antibody-mediated rejection M Mengel, B Sis, M Haas, RB Colvin, PF Halloran, LC Racusen, K Solez, ... American Journal of Transplantation 12 (3), 563-570, 2012 191
- Banff 2013 Meeting Report: Inclusion of C4d-Negative Antibody-Mediated Rejection and Antibody-Associated Arterial Lesions M Haas, B Sis, LC Racusen, K Solez, D Glotz, RB Colvin, MCR Castro, ... American Journal of Transplantation 14 (2), 272-283, 2014 148

American Journal of Transplantation 2007; 7: 2221-2226
Blackwell Munksgaard

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doi: 10.1111/j.1600-6143.2007.01924.x

Personal Viewpoint

SWOT Analysis of Banff: Strengths, Weaknesses, Opportunities and Threats of the International Banff Consensus Process and Classification System for Renal Allograft Pathology

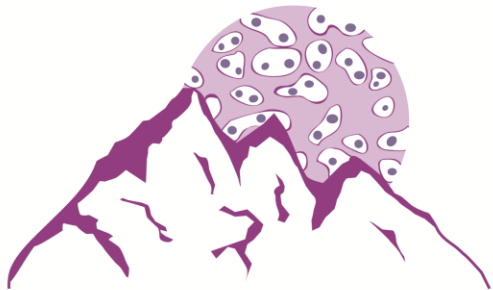
M. Mengel^{a,*}, B. Sis^{a,b} and P. F. Halloran^a

pathology, which is needed for research, clinical trials and patient management. The consensus process involves in

History and Background:

Banff Foundation For Allograft Pathology

- August 2011, 11th Banff meeting, Paris: Identified unmet need for a formal organizational structure for the Banff process
- Nov 2011: MOU of Key opinion Leaders from the informal Banff Process
- October 2012: Grant application to ROTRF “*Creation of Swiss Foundation Legal Entity for the Banff Allograft Pathology Classification and Consensus Process*”
- January 30. 2013: Application for establishing Swiss non for profit foundation approved by Swiss authorities
- March 2013: ROTRF funding approval supplying three-year grant funding for establishing the “**Banff Foundation For Allograft Pathology**”: [www. http://banfffoundation.org/](http://banfffoundation.org/)



BANFF FOUNDATION
FOR ALLOGRAFT PATHOLOGY

BANFF Foundation (CHE-203.115.238) - Luzernerstrasse 36 - 6045
Meggen – Switzerland

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Purpose of Banff Foundation

- The purpose of the Foundation is to promote collaborative research and refinement of knowledge in the field of transplantation pathology and related diagnostics worldwide.
- The foundation has a not for profit purpose and does not have to generate a profit.
- The ultimate objective of the research being supported is to facilitate knowledge translation and constant evolution of allograft pathology and related diagnostics in order to enhance clinical care and improve outcomes in transplant recipients.
- The results of the research activities supported will be published in the annual Banff Foundation report, on the Foundation website or in scientific journals, and will be presented at international scientific meetings.
- In particular, support will be provided to research projects of the Banff Working Groups (BWG) designed to create and evaluate data-driven and evidence-based refinement of the Banff classifications.

Banff Working Groups (BWG)

Loupy et al

Table 1: Summary of active Banff 2015 working groups

	Leaders	Issues to address	Group findings/plans
TCMR	V. Nickeleit, P. Randhawa	Possible incorporation of i-IFTA into classification; possible elimination of borderline category; reevaluate thresholds for inflammation and t and possible addition of other findings (e.g. edema) to TCMR diagnostic criteria	Group currently collecting cases of "pure" TCMR (no DSA or C4d) for pathologic evaluation and clinicopathologic correlation
Sensitized	L. Cornell, E. Kraus, S. Bagnasco, C. Schinstock, D. Dadhania	Define criteria for HS patients, determine consensus for what personnel and facilities are needed for centers to perform transplantation in HS recipients, standardize the definitions related to management of sensitized transplant recipients	Survey results presented by L. Cornell at 2015 Banff conference; expanded survey, future discussions to address core issues; prepare consensus paper for publication
Molecular	M. Mengel, B. Sis	Develop consensus guidelines for circumstances under which it is advisable to apply molecular analysis to renal biopsy tissue and/or serum/urine collected at the time of biopsy; determine the best molecular studies to perform with the aim of generating the needed evidence for adoption of molecular diagnostics into the Banff classification; standardize diagnostic criteria for molecular microscope	Single-center data using the NanoString method on FFPE tissue presented by Banu Sis at the Banff 2015 conference; validation needed of biopsies from additional centers
Electron microscopy	C. Roufosse, H.K. Singh	Interobserver variability and clinical correlations in cg1a lesions and ptcmI scoring; potential refinement of ptcmI scoring criteria; criteria for amount of GBM reduplication and immune complex-type deposits allowable in cg1a; multicenter study of the natural history, associations, and predictive value of cg1a and ptcmI using consensus criteria	Survey of current practice completed June 2016; circulation of images for interobserver reproducibility, fall 2016; multicenter study 2017–2018
TMA ¹	M. Afrouzian, J. Becker, H. Liapis, S. Seshan	Generate consensus regarding diagnostic criteria for TMA in renal allografts using histopathology/laboratory data/molecular genetics correlation	Survey 1 circulated in January 2016; results have been shared with the working group participants. Plan: TMA experts defined and identified; will collect ~30 cases; generate virtual slides and run digital evaluation
Recurrent glomerular disease ¹	N. Alachkar	Focus on glomerulopathies: IgA nephropathy, FSGS, MPGN/C3 glomerulopathy; what are frequencies, clinical manifestations, and pathologic characteristics of recurrent/ <i>de novo</i> disease? Can any of these predict recurrence and/or graft outcomes?	New working group
Composite surrogate end points ¹	A. Loupy, B. Orandi	Respond to the unmet need raised by the FDA meeting held in Arlington, Virginia, in 2015: Build a validated multicenter composite scoring system integrating histopathology with other relevant allograft biomarkers to predict long-term allograft outcome	New working group

cg, glomerular double contours; DSA, donor-specific antibody; FDA, U.S. Food and Drug Administration; FFPE, formalin-fixed, paraffin-embedded; FSGS, focal segmental glomerulosclerosis; GBM, glomerular basement membrane; HS, highly sensitized; i-IFTA, interstitial inflammation in areas of interstitial fibrosis and tubular atrophy; MPGN, membranoproliferative glomerulonephritis; ptcmI, peritubular capillary basement membrane multilayering; t, tubulitis; TCMR, T cell-mediated rejection; TMA, thrombotic microangiopathy.

¹New working group.

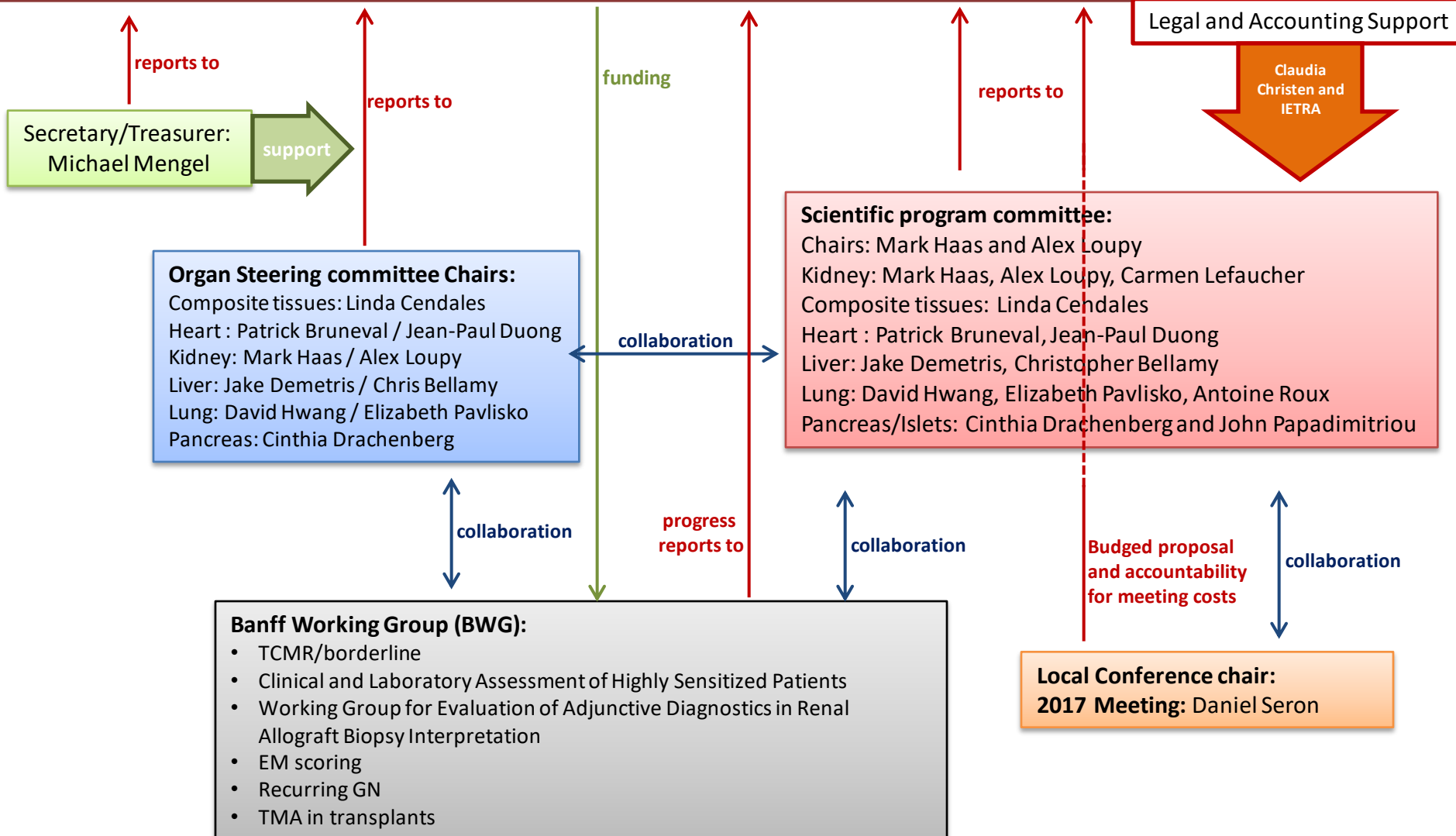
Banff Working Groups:

- Require BOT approval
- Must address an unmet need in the Banff classification
- Need to be productive and report progress at Banff meetings
- Are temporary: discontinued if not productive in addressing the unmet need in reasonable time frame

Organizational structure of the Banff Foundation

Board of Trustees:

K. Solez (Chair), L. Racusen, D. Glotz, A. Demetris, M. Mengel, M. Mihatsch, D. Seron, B. Nankivell, A. Loupy



2017 Financial Report

Revenue: 2013-2016

- ROTRF grant: 120k
- Industry grants: 45k
- Banff meetings: 180k
- Donations: 0k

- No membership fees
- No endowment

Expenses: 2013-2016

- Foundation operation: 85k
- Banff meeting: 50k
- Banff Working Groups: 10k
- Publications: 15k

Current balance: +184,744 CHF

- MOU developed in July 2016
- Joint Oversight committee
- Joint Program committee



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2017 BANFF-SCT Joint Scientific Meeting

BARCELONA

27-31 March 2017



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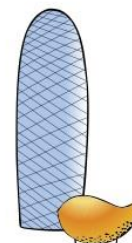
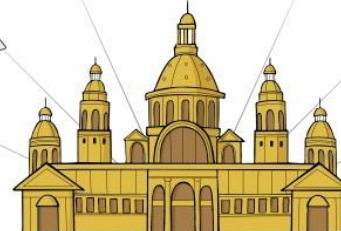
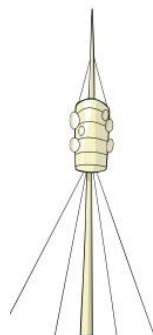
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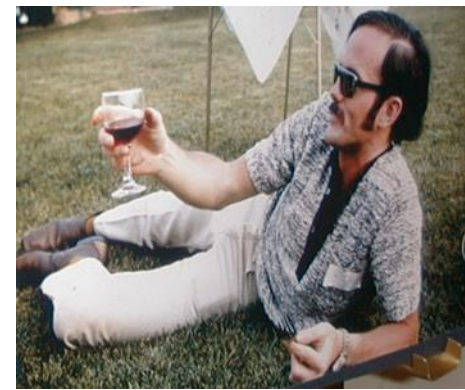
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Final programme



Acknowledgements



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