Consensus Statement

After a review of best current evidence and subsequent breakout discussions, consensus was achieved on all of the items discussed, as outlined below.

1. **Adjuvant Therapy Colon Carcinoma**

**Is FOLFOX the best available adjuvant regimen for colon cancer? Has the most recent update of the data solidified the therapeutic benefit?**

It was unanimously agreed that regimens containing Oxaliplatin and a fluoropyrimidine (FU) are preferred for people resected with curative intent high-risk colon carcinoma requiring adjuvant therapy. Two randomized controlled trials have shown a significant improvement in disease free survival in comparison to FU containing regimens alone.

It is imperative that patients in Western Canada with colorectal cancer have equal access to Oxaliplatin. A situation in which patients in one Western province have access to this therapy but not those in neighboring provinces is unacceptable. Without access to this agent, it is impossible to be able to offer the best treatment options for Canadian colorectal cancer patients. PROVINCIAL GOVERNMENTS CAN OBVIOUSLY APPROVE THIS WITHOUT REGISTRATION AS HAS BEEN DONE IN SOME PROVINCES ALREADY.

For patients with low-risk stage II colon cancer (no poor prognostic factors) and an adequate lymph node dissection (evaluation of twelve or more regional lymph nodes in the resected specimen), no further therapy other than appropriate surveillance should be recommended.

**In patients for whom oxaliplatin is not appropriate, what is the recommended standard for adjuvant colon cancer therapy?**

Consensus was reached that current data does support the use of capecitabine in this setting. There was consensus that this would be the preferred treatment option over 5FU/Leucovorin given the favorable toxicity profile of Capecitabine. Current data does not support the use of Irinotecan in the adjuvant setting.

2. **Use of Biologics in the treatment of Metastatic Colorectal Carcinoma**

**Does current evidence support the use of targeted agents (Bevacizumab and Cetuximab) as new standards of care? If so, in what setting should they be used?**

Evidence from randomized phase III trials supports a survival advantage for Bevacizumab in combination with fluoropyrimidine based therapy in first line treatment of stage IV colorectal cancer. In selected patients who are Bevacizumab naïve, second line chemotherapy in combination with Bevacizumab is also supported by phase III evidence, with a smaller survival advantage. The use of Bevacizumab beyond disease progression was not supported. The recommended dose of Bevacizumab is 5mg/kg with q2weekly infusional FU-based regimens and 7.5mg/kg if used with q3weekly Capecitabine.

Phase II evidence suggests that Cetuximab in combination with Irinotecan increases response rates in the third line setting. Further evidence from ongoing randomized trials is needed before the routine use of this agent can be supported.
3. Rectal Carcinoma Therapy

What is the recommended treatment protocol for the treatment of rectal carcinoma?

TME surgical resection is recommended for all resectable rectal cancer patients.

Clinical T1/T2 N0M0 should proceed directly to surgical resection.

A multidisciplinary preoperative assessment is recommended. Investigations with pelvic MRI and/or TRUS should be used to assess resectability.

Patients with no evidence of metastatic disease after conventional staging investigations and with

• Clinical evidence of fixation, or
• Radiological evidence of a T4 tumor, or
• Radiological evidence of a T3 tumor with a concern about the ability to obtain adequate resection margins, or
• Clinical and/or radiological evidence a low-lying lesion where sphincter preservation is desired

should be considered for long-course pre-operative therapy followed by definitive surgery, and then standard adjuvant 5-fluorouracil-based therapy.

Patients with an unequivocal T3 tumor in the upper rectum on both clinical and radiological assessment may be considered for immediate surgical resection or short-course pre-operative radiotherapy followed by definitive surgery within seven to ten days, both options to be followed by standard adjuvant 5-fluorouracil-based chemotherapy.

Patients with a post-operative diagnosis of stage II and stage III rectal cancer (for whom prior therapy has not been offered) warrant standard adjuvant 5-fluorouracil-based chemotherapy and radiotherapy.

Is there enough data to recommend one of either short course or long course radiotherapy?

It was felt that at this time, there is insufficient evidence to support the use of one approach over the other. The ongoing phase III trial by the Polish Rectal Cancer Trial Group will be addressing this issue.