



Impact of the IDEA Collaboration Study Results on Clinical Practice in France for Patients With Stage III Colon Cancer: A National GERCOR - PRODIGE Survey

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Abstract

The IDEA study showed that the type and duration of adjuvant chemotherapy might be adjusted according to the schedule of chemotherapy (5-fluorouracil, leucovorin, and oxaliplatin [FOLFOX] or capecitabine and oxaliplatin [CAPOX]) and the level of risk in stage III colon cancer. Hereby, we show that it has been mainly integrated in routine practice in France with a switch from 6 to 3 months and from the FOLFOX to the CAPOX regimen in patients with low-risk stage III colon cancer.

Background: The IDEA collaboration showed that the type and duration of adjuvant chemotherapy in stage III colon cancer (CC) could be adjusted according to the schedule of chemotherapy and the level of risk. We aimed at evaluating the implementation of IDEA's results in real-life practice for stage III CC. **Material and Methods:** All clinicians registered in the French oncology cooperative groups GERCOR, FFCD, and UNICANCER GI mailing lists were invited to participate to an online anonymized nationwide survey from January 30, 2019 to March 31, 2019. Proportions were compared using the χ^2 test. **Results:** A total of 213 physicians answered the survey. Of these, 173 (81%) considered that 3 months of adjuvant chemotherapy was the new standard of care for low-risk (pT1-3/N1) stage III CC, and 99% considered that 6 months remained the standard of care for high-risk (pT4 and/or pN2) stage III CC. In patients under 70 years, capecitabine and oxaliplatin (CAPOX) for 3 months was prescribed by 74% of the participants in low-risk CC, whereas 6 months of 5-fluorouracil, leucovorin, and oxaliplatin (FOLFOX) was preferred for high-risk CC in 94% of cases. For patients over 70 years with good performance status and no comorbidities, 172 (81%) physicians prescribed oxaliplatin-based chemotherapy for low-risk CC (3 months, 144 of 172%; 88%), and 200 (94%) physicians prescribed oxaliplatin-based adjuvant chemotherapy for high-risk CC (6 months, 199 of 200%; 99.5%). **Conclusions:** The IDEA results have been practice-changing as French physicians have implemented 3 months of CAPOX for patients with low-risk stage III CC, substituting from 6 months of FOLFOX, which remains the preferred regimen for high-risk patients.

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Introduction

Six months of adjuvant chemotherapy with oxaliplatin plus a fluoropyrimidine has been the standard of care for patients with stage III colon cancer (CC) since 2004.¹⁻⁴ However, the cumulative neurotoxicity related to the use of oxaliplatin led to the evaluation of a shortened duration of adjuvant chemotherapy in this setting.

The IDEA (International Duration Evaluation of Adjuvant Therapy) collaboration study showed that the type and duration of adjuvant chemotherapy in stage III CC might be adjusted according to the level of risk (low-risk: pT1-3 and pN1; high-risk: pT4 and/or pN2).⁵ Although the study did not demonstrate the non-inferiority of 3 months versus 6 months of adjuvant chemotherapy in the overall population for disease-free survival (DFS) (hazard ratio [HR], 1.07; 95% confidence interval [CI], 1.00-1.15), the non-inferiority of CAPOX (capecitabine plus oxaliplatin) for 3 months was demonstrated for patients with low-risk stage III CC, which represents 59% of the entire stage III population.

International guidelines⁶⁻⁸ have been updated accordingly, but data concerning the implementation of the IDEA conclusions in real-life adjuvant chemotherapy prescriptions are lacking. We aimed at assessing the impact of the IDEA study on daily practice for stage III CC in France.

Material and Methods

Physicians registered in 3 French cooperative groups (Fédération Francophone de Cancérologie Digestive [FFCD]; French Multidisciplinary Group in Oncology [GERCOR]; and Unicancer Gastrointestinal Group [UCGI]) were invited to fill in an online questionnaire (see [Supplemental Methods](#) in the online version). Reminder emails were sent every 2 weeks. The survey was composed of 24 questions, related to daily practices. Clinicians were asked which modality of adjuvant chemotherapy (5-fluorouracil, leucovorin, and oxaliplatin [FOLFOX] or CAPOX, 3 months or 6 months) they would choose in different clinical settings. A 5-point Likert scale was also used (from 1, strongly disagree, to 5, strongly agree) to evaluate IDEA's impact on their daily clinical practice. Participants were also asked to indicate the preferred venous access (peripheral or central access) and device (peripherally inserted central catheter [PICC] line or implanted port). Answers were declarative, individual, and anonymized. Proportions were compared using χ^2 tests. The level of significance was $P < .05$.

Results

A total of 213 physicians participated in the survey from January 30, 2019 to March 31, 2019. Demographic characteristics are displayed in [Supplemental Table 1](#) (in the online version). One hundred ninety-eight of them completed the survey in its entirety. Of the participants, 63% agreed or strongly agreed that the IDEA study had an impact on their clinical practice, whereas 17% disagreed or strongly disagreed. Seventy-five percent declared that 3 months of CAPOX was the new standard of care for patients with low-risk stage III CC. Physicians working in academic hospitals, compared with those working in general hospitals, were more likely to consider 3 months of CAPOX as the new standard (88% vs. 63%; $P = .002$). The same trend was observed between gastroenterologists and medical oncologists (82% vs. 63%; $P = .03$) and

between physicians with more than 12 patients with stage III CC per year compared with those with less than 4 patients per year (70% vs. 50%; $P = .018$). Ninety-nine percent of the participants considered that 6 months of adjuvant chemotherapy remained the standard of care for the high-risk population.

Patients Under 70 Years

For patients with low-risk stage III CC, adjuvant chemotherapy was prescribed for 3 months by 84% of the responders, with a majority using the CAPOX regimen (75% vs. 8% with FOLFOX); a 6-month duration of adjuvant chemotherapy was chosen by 16% of physicians (with FOLFOX only) ([Figure 1](#)).

For patients with high-risk stage III CC, 94%, 5.5%, and 0.5% of physicians prescribed FOLFOX for 6 months, CAPOX for 6 months or FOLFOX for 3 months, respectively.

Patients Over 70 Years

Eastern Cooperative Oncology Group Performance Status (ECOG PS) 0 to 1 and No Comorbidity. For patients > 70 years with good ECOG PS and low-risk stage III CC, oxaliplatin-based chemotherapy was prescribed by 81% of physicians, for 3 (68%) or 6 (13%) months. Eighteen percent of responders chose fluoropyrimidine monotherapy for 3 (3%) or 6 (15%) months ([Figure 2](#)).

For patients with high-risk stage III CC, adjuvant chemotherapy was prescribed for 6 months by 99.5% of responders, mainly with doublets (94%, whereas 6% chose fluoropyrimidine monotherapy).

ECOG PS > 1 and/or With Comorbidities. For older patients with altered ECOG PS or comorbidities, in case of low-risk stage III CC, 13%, 61%, and 25% of the participants declared to prescribe no adjuvant chemotherapy, fluoropyrimidine monotherapy, or oxaliplatin-based chemotherapy, respectively. Oxaliplatin-based adjuvant chemotherapy was proposed for 3 months by most (65%) clinicians.

In the high-risk population with ECOG PS > 1 or comorbidities, 3%, 44%, and 51% said they prescribed no adjuvant chemotherapy, a fluoropyrimidine alone, or oxaliplatin-based chemotherapy (94% for 6 months), respectively.

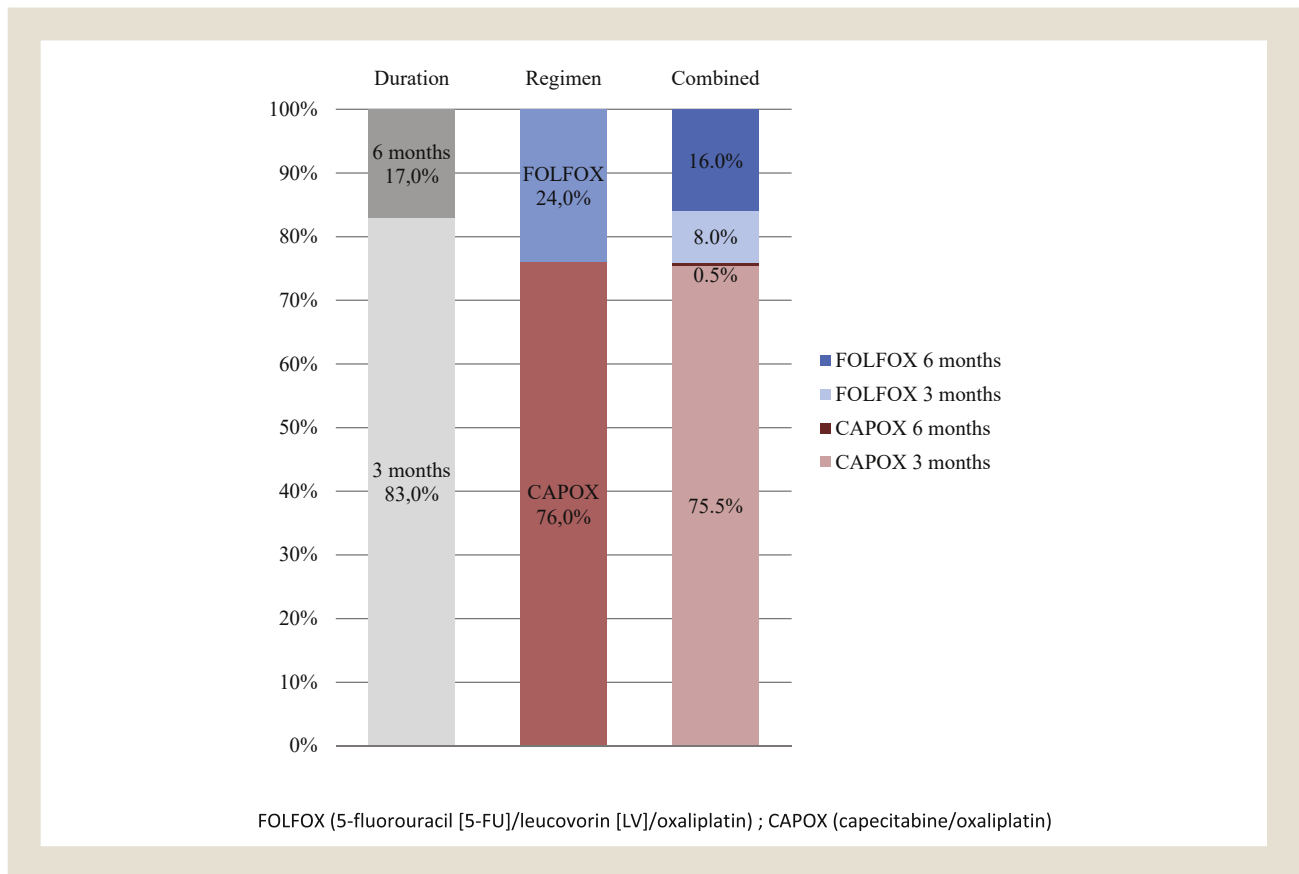
Venous Access

In patients with appropriate venous capital, CAPOX for 3 months was administered without central venous access device (CVAD) for two-thirds (66%) of the participants, using an implantable port (21%) or a PICC line (12%).

Discussion

Our study is the first to report real life practices for patients with stage III CC after the publication of the IDEA study. We show that the modulation of adjuvant chemotherapy duration and type according to the level of risk has been adopted as standard of care in France for patients with stage III CC.

Our results are in line with a survey realized among the Australia and New Zealand SCOT's participants. It reported that the expected minimum survival benefit warranted to choose a 6-month adjuvant chemotherapy rather than 3-month duration was much larger than the estimates of the IDEA trial.⁹ One might have

Figure 1 Type and Duration of Adjuvant Chemotherapy For Patients Under 70 Years With Low-risk Stage III Colon Cancer

Abbreviations: CAPOX = capecitabine and oxaliplatin; FOLFOX = 5-fluorouracil, leucovorin, and Oxaliplatin.

hypothesized that CAPOX might not be easily integrated into daily practice in France because FOLFOX was prescribed by a vast majority of French physicians before (90% in the IDEA France trial¹⁰). Although the FOLFOX regimen remained largely prescribed for patients with high-risk stage III CC, the combination of capecitabine and oxaliplatin was the main choice for patients with low-risk stage III CC in this survey, showing how much impact IDEA had on real-life patients' care.

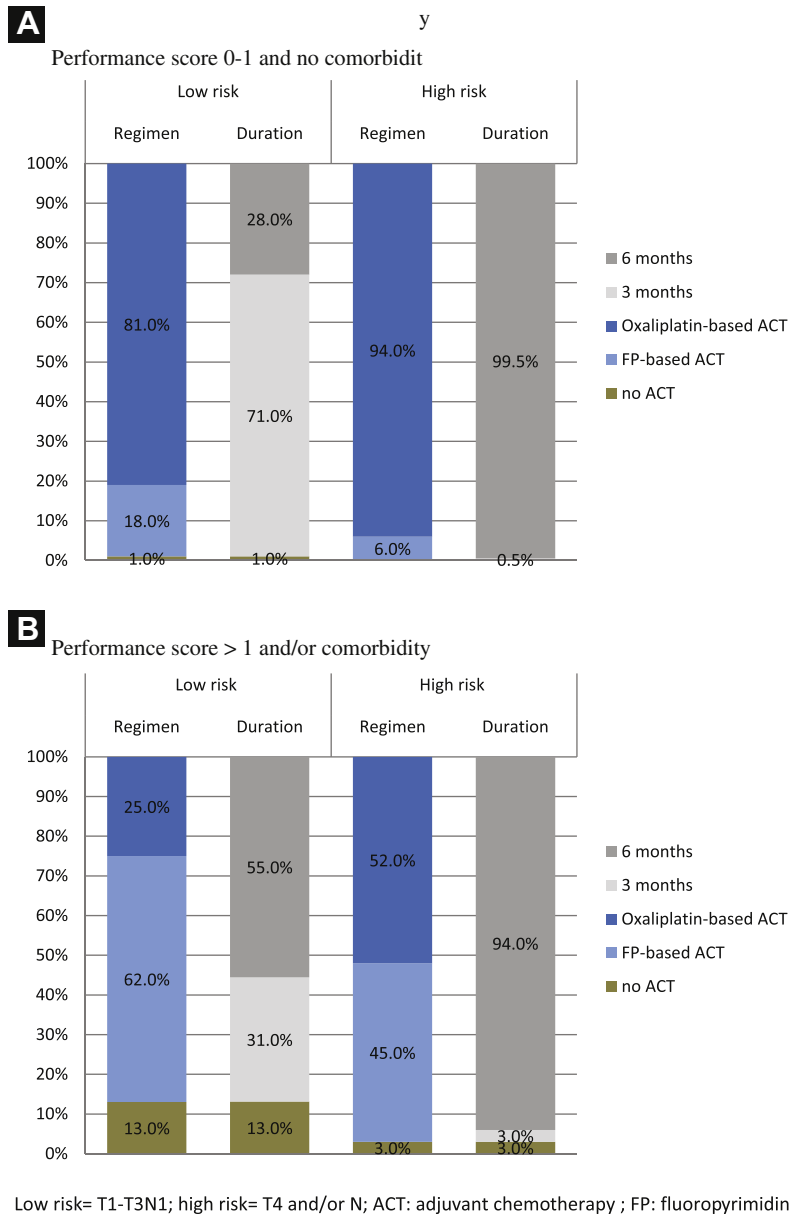
Oxaliplatin-based adjuvant chemotherapy was mostly prescribed for older patients with good ECOG PS (80%-90%) and, to a lesser extent, for patients with comorbidities and high-risk CC (50%). However, there is no clear evidence that the addition of oxaliplatin to fluoropyrimidine is associated with an improvement of DFS or OS in patients older than 70 years, as it has been shown in a pooled analysis of the MOSAIC, NSABP C-07, and XELOXA trials (N = 1119; DFS HR, 0.94; 95% CI, 0.78-1.13 and OS HR, 1.04; 95% CI, 0.85-1.27).^{11,12} Another analysis from the NSABP C-08, XELOXA, X-ACT, and AVANT trials, though, did detect a significant improvement of DFS and OS in patients > 70 years treated with XELOX (capecitabine and oxaliplatin) or FOLFOX.¹³ The prescription of doublet adjuvant chemotherapy in fit elderly patients observed in our survey remains to be properly evaluated in dedicated clinical trials, such as the PRODIGE 34 phase III study (NCT023553790).

One-third of the physicians used CVAD for patients treated with CAPOX for 3 months, despite good venous capital. The feasibility of treating patients with CAPOX on a peripheral venous access for 3 or 6 months has been demonstrated in an analysis of 203 patients included in the IDEA France study: CAPOX adjuvant chemotherapy without a CVAD was successful in 88.4% of patients for whom chemotherapy had been planned without the use of CVAD.¹⁴ The reason why one-third of physicians use central venous devices needs to be explored.

Our study exhibits several weaknesses. First, the study population might have been biased by its selection through the cooperative group networks, even if it is representative of the current French medical demography,¹⁵ with physicians working in different types of institutions, with various levels of experience and different medical specialty backgrounds. Interestingly, we observed the level of changes in clinical practice varied depending on the participants' characteristics, the prescription of adjuvant therapy for 3 months being more frequent in academic hospitals and among physicians taking care of more than 12 patients with stage III CC per year.

We acknowledge that the declarative nature of our study might have biased the results. We observed that the declared frequency of use of CAPOX for 3 months was lower than the proportion of physicians declaring this treatment as the new standard of care: 44% of physicians declared they prescribed it for their last 5 patients with

Figure 2 Type and Duration of Chemotherapy For Patients > 70 Years With Low-risk or High-risk Stage III Colon Cancer, Depending on Performance Status and Comorbidities. A, Performance Score 0 to 1 and no Comorbidity. B, Performance Score > 1 And/Or Comorbidity



Abbreviations: ACT = adjuvant chemotherapy; FP = fluoropyrimidine; high-risk = T4 and/or N; low-risk = T1-T3N1.

low-risk stage III tumors, whereas 75% of them declared considering CAPOX 3 months as the new standard of care for this population. Therefore, analyses of prospective cancer registries are required to validate our study. In addition, it would be interesting to evaluate if the recent release of OS data from the IDEA study reinforced the observed changes in routine practice.¹⁶

To conclude, adjuvant chemotherapy with CAPOX for 3 months has been mainly integrated as a new standard of care for patients with low-risk stage III CC. FOLFOX for 6 months remains the

preferred choice of prescribers for patients with high-risk disease in France.

Clinical Practice Points

- The prospective, pre-planned pooled analysis of 6 concurrently conducted randomized phase III trials (IDEA collaboration) was built to evaluate the non-inferiority of 3 months of adjuvant treatment with oxaliplatin plus fluoropyrimidine to the 6-month standard duration of therapy for patients with stage III CC.

Although the non-inferiority was not confirmed in the overall population, the IDEA study showed that the type and duration of treatment may be adjusted according to the level of risk (low risk pT1-3/N1 vs. high risk pT4 and/or N2).

- We conducted a nationwide survey in France, 1 year after the publication of the IDEA collaboration results. We show that a shortened duration of adjuvant treatment using CAPOX for 3 months has been integrated in France as standard of care for patients with low-risk stage III CC by most physicians. In this survey, 6 months of FOLFOX remains the standard treatment for the high-risk population.

Disclosure

BR reported honoraria for speaker or advisory role from Astellas, Bayer, Gilead, Novartis, Roche, and Astellas; research funding from Roche/Foundation Medicine; and travel, accommodations, and expenses from Bayer and Servier. CN reported honoraria for speaker or advisory role from Servier, AstraZeneca, Amgen, Merck, Novartis, Incyte, Baxter, and MSD; research funding from Roche/Foundation Medicine; and travel, accommodations, and expenses from OSE Immunotherapeutics, MSD, Merck, and Mylan. ES reports honoraria from Pierre Fabre, Roche, Servier, Amgen, Sanofi, Bristol-Myers Squibb, and MSD Oncology and travel from Servier, Roche, MSD, and Amgen. JT reported honoraria for speaker or advisory role and travel and accommodation grants from Celgene, Roche, Merck, MSD, Lilly, HalioDX, Sanofi, Amgen, Servier, Pierre Fabre, and Sirtex. RC reported honoraria from Amgen, Sanofi and Servier, and travel fees from Sanofi. TA reported a consulting or advisory role and or honoraria from Bristol-Myers Squibb, Clovis, GlaxoSmithKline, HalioDX, MSD Oncology, Pierre Fabre, Roche/Genentech/Ventana, Sanofi, Servier, and Teasaro; speakers' bureau for Bristol-Myers Squibb and Servier; travel, accommodations, and expenses from Amgen, Bristol-Myers Squibb, Roche, and Ventana. The remaining authors have stated that they have no conflicts of interest.

Supplemental Data

Supplemental data accompanying this article can be found in the online version at <https://doi.org/10.1016/j.clcc.2020.11.004>.

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Supplemental Data

Supplemental Table 1 Population Characteristics	
	N (%)
Participants	213 (100)
Specialty	
Gastroenterologist	109 (51)
Medical oncologist	84 (39)
Radiation therapist	10 (5)
Surgeon	10 (5)
Workplace	
Academic hospital	65 (31)
General hospital	57 (27)
Comprehensive cancer center	56 (26)
Private clinic	35 (16)
Experience in gastro-intestinal cancers	
<5 years	28 (13)
5-10 years	40 (19)
10-20 years	75 (35)
>20 years	70 (33)
Number of patients with stage III colon cancer	
<4 per year	10 (5)
4-8 per year	53 (25)
8-12 per year	51 (24)
>12 per year	99 (46)

Supplemental Methods Questionnaire

PART I:

- In which region are you working:
 - Auvergne-Rhône-Alpes
 - Bourgogne-Franche-Comté
 - Bretagne
 - Centre-Val de Loire
 - Corse
 - Grand-Est
 - Hauts-de-France
 - Ile-de-France
 - Normandie
 - Nouvelle-Aquitaine
 - Occitanie
 - Pays de la Loire
 - Provence-Alpes-Côte d'Azur
 - DOM-TOM
- Do you work:
 - In a teaching hospital
 - In a general hospital
 - In a private health institution of collective interest/ Comprehensive cancer center
 - In a private clinic
 - Other

- Number of years of practice:
 - < 5 years
 - Between 5 and 10 years
 - Between 10 and 20 years
 - > 20 years
- What is your specialty:
 - Medical oncologist
 - Radiation oncologist
 - Gastro-enterologist with an expertise in oncology
 - Surgeon
 - Other
- Number of patients with a stage III colon cancer or high rectal cancer that you newly took care of in the last 12 months:
 - < 4 patients
 - Between 4 and 8 patients
 - Between 8 and 12 patients
 - > 12 patients

PART II:

- Since the publication of the IDEA study (Grothey A, et al. Duration of Adjuvant Chemotherapy for Stage III Colon Cancer. *N Engl J Med* 2018; 378:1177-88), did you change your practices?
Likert scale from 0 (not at all) to 10 (completely).

Concerning the duration of treatment:

- For the T1-T3 and N1 tumors, concerning the duration of treatment:
 - Yes, 3 months is the new duration for the majority of my patients in this case
 - No

If you answered no, why? (multiple replies are possible):

- The study does not allow to conclude noninferiority on its main judgment criteria
- The analysis of the results by level of risk (stage III of low risk versus high risk) was not planned in the protocol; so I don't think this subgroup analysis is robust enough
- The analysis of the IDEA France study show that 6 months of FOLFOX is better than 3 months of FOLFOX, even for the low risk, and I prefer to use FOLFOX
- Other: *Specify [free text]*

- For the T4 and/or N2 tumors, concerning the duration of treatment:
 - Yes, 3 months is the new duration for the majority of my patients in this case
 - No

If you answered no, why? (multiple replies are possible):

- The study shows the superiority of 6 month in this subgroup
- The analysis of the results by level of risk (stage III of low risk versus high risk) was not planned in the protocol and does not allow to conclude statistically

- at the noninferiority of 3 months vs 6 months, so sub-group analyses don't seem valid to me
- c. The analysis of the IDEA France study showing that 6 months of FOLFOX is better than 3 months of FOLFOX.
 - d. Other: *Specify [free text]*

Concerning the treatment regimen:

4. For the T1-T3 and N1 tumors, concerning the treatment regimen:
 - A. Yes, CAPOX is the treatment regimen that I prescribe to the majority of my patients in this case, and I prescribe it for 3 months
 - B. Yes, CAPOX is the treatment regimen that I prescribe to the majority of my patients in this case, and I prescribe it for 6 months
 - C. No

If you answered no, why? (multiple replies are possible):

- a. the analysis of the IDEA France study shows that 6 months of FOLFOX is better than 3 months of FOLFOX.
- b. I'm rather partial to FOLFOX6m for tolerance reasons.
- c. I'm rather partial to FOLFOX6m for observance reasons.
- d. Other: *Specify [free text]*

5. For the T4 and/or N2 tumors, concerning the treatment regimen:
 - A. Yes, CAPOX is the treatment regimen that I prescribe to the majority of my patients in this case, and I prescribe it for 3 months
 - B. Yes, CAPOX is the treatment regimen that I prescribe to the majority of my patients in this case, and I prescribe it for 6 months
 - C. No

If you answered no, why? (multiple replies are possible):

- a. The analysis of the IDEA France study shows that 6 months of FOLFOX is better than 3 months of FOLFOX.
- b. I'm rather partial to FOLFOX6m for tolerance reasons.
- c. I'm rather partial to FOLFOX6m for observance reasons.
- d. Other: *Specify [free text]*

PART IIIA: In the case of a patient under 70 years of age in good shape with a stage III colon cancer or high rectal cancer treated by surgery:

1. If this was a stage pT3N1:
 - a. What treatment regimen would you propose as first-line therapy?
 - A. CAPOX
 - B. FOLFOX

- b. For how long?
 - A. 3 months
 - B. 6 months
2. For the last 5 patients under 70 years of age you took care of for a pT3N1, to how many did you prescribe:
 - A. CAPOX 3 months: (n)
 - B. CAPOX 6 months: (n)
 - C. FOLFOX 3 months: (n)
 - D. FOLFOX 6 months: (n) [A+B+C+D=5]
 3. If this was a stage pT3N2:
 - a. What treatment regimen would you propose as first-line therapy?
 - A. CAPOX
 - B. FOLFOX
 - b. For how long?
 - A. 3 months
 - B. 6 months
 4. If this was a stage pT4N1:
 - a. What treatment regimen would you propose as first-line therapy?
 - A. CAPOX
 - B. FOLFOX
 - b. For how long?
 - A. 3 months
 - B. 6 months
 5. If this was a stage pT4N2:
 - a. What treatment regimen would you propose as first-line therapy?
 - A. CAPOX
 - B. FOLFOX
 - b. For how long?
 - A. 3 months
 - B. 6 months
 6. For the last 5 patients under 70 years of age you took care of for a pT4 or N2, to how many did you prescribe:
 - A. CAPOX 3 months: (n)
 - B. CAPOX 6 months: (n)
 - C. FOLFOX 3 months: (n)
 - D. FOLFOX 6 months: (n) [A+B+C+D=5]

PART IIIB: In the case of a patient over 70 years of age in good shape (OMS 0 or 1, without co-morbidities) with a stage III colon cancer or high rectal cancer treated by surgery:

1. If this was a stage pT3N1:
 - a. What treatment regimen would you propose as first-line therapy?
 - A. Simple monitoring
 - B. CAPECITABINE
 - C. LV5FU2
 - D. CAPOX
 - E. FOLFOX
 - b. For how long?
 - A. 3 months

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- B. 6 months
- C. Not applicable (Simple monitoring)
- c. About the last 5 patients you took care of, how many did you treat with:
 - A. Simple monitoring: (n)
 - B. CAPECITABINE: (n)
 - C. LV5FU2: (n)
 - D. CAPOX: (n)
 - E. FOLFOX: (n) [$A+B+C+D+E=5$]
- d. Based on your chemotherapy prescription data, for those who had chemotherapy, what was the duration of treatment?
Likert scale: Always 3 months/mainly 3 months/as much 3 months as 6 months/mainly 6 months/always 6 months
- 2. If this was a stage pT4N2:
 - a. What treatment regimen would you propose as first-line therapy?
 - A. Simple monitoring
 - B. CAPECITABINE
 - C. LV5FU2
 - D. CAPOX
 - E. FOLFOX
 - b. For how long?
 - A. 3 months
 - B. 6 months
 - C. Not applicable (Simple monitoring)
 - c. About the last 5 patients you took care of, how many did you treat with:
 - A. Simple monitoring: (n)
 - B. CAPECITABINE: (n)
 - C. LV5FU2: (n)
 - D. CAPOX: (n)
 - E. FOLFOX: (n) [$A+B+C+D+E=5$]
 - d. Based on your chemotherapy prescription data, for those who had chemotherapy, what was the duration of treatment?
Likert scale: Always 3 months/mainly 3 months/as much 3 months as 6 months/mainly 6 months/always 6 months

PART IIIC: In the case of a patient over 70 years of age in good shape, but OMS 2 or with co-morbidities, with a stage III colon cancer or high rectal cancer treated by surgery:

- 1. If this was a stage pT3N1:
 - a. What treatment regimen would you propose as first line therapy?
 - A. Simple monitoring
 - B. CAPECITABINE
 - C. LV5FU2
 - D. CAPOX
 - E. FOLFOX
 - b. For how long?
 - A. 3 months
 - B. 6 months
 - C. Not applicable (Simple monitoring)
- 2. a. During the realization of an adjuvant chemotherapy by CAPOX during 3 months, in case of good clinical venous state, do you preferentially do the treatment on:
 - A. An importable port
 - B. A PICC-line
 - C. A peripheral venous line
- b. Of the 5 last patients for whom you prescribed CAPOX for 3 months, to how many did you do the treatment on:
 - A. An implantable port: X
 - B. A PICC-line: Y
 - C. Not on a central line: Z [$X+Y+Z=5$]
- 2. a. During the realization of an adjuvant chemotherapy by CAPOX during 6 months, in case of good clinical venous state, do you preferentially do the treatment on:
 - A. An importable port
 - B. A PICC-line
 - C. A peripheral venous line

- b. Of the 5 last patients for whom you prescribed CAPOX for 3 months, to how many did you do the treatment on:
 - A. An implantable port: X
 - B. A PICC-line: Y
 - C. Not on a central line: Z [$X+Y+Z=5$]
- 3. When you decided to do a chemotherapy by CAPOX on a peripheral venous line,
 - a. In which proportion of the cases you had to secondarily put a central line (an importable port or a PICC-line) during treatment:
 - A. Less than 25%
 - B. Between 25% and 50%
 - C. Between 50% and 75%

- D. More than 75%
 - b. Was it:
Likert scale: Always an importable port/mainly an importable port/as much an importable port as a PICC-line/mainly a PICC-line/always a PICC-line
 - c. What was the reason for secondary use of a peripheral venous line? [*free text*]
- 4. When you decide to do a chemotherapy by FOLFOX, do you do:
 - A. FOLFOX6m (1 infuser of 46h)
 - B. FOLFOX4 (2 infuser of 23h)