

SCRI Trials and Trial Regimen Updates

The following updates were completed between Nov. 15, 2024, and Dec. 12, 2024. Sarah Cannon Research Institute now manages all SCRI/USOR trials and trial regimens. For questions about these trials and regimens, please contact SCRiKMEMRedits@McKesson.com.

New Builds Completed

Study Number	Notes for New Build
23190	USOR 23190 GYN 124 Phase 3 Arm 1 MK-2870 Q14D USOR 23190 GYN 124 Phase 3 Arm 2 Doxorubicin Q21D USOR 23190 GYN 124 Phase 3 Arm 2 Paclitaxel D1,8,15 Q28D
24106	USOR 24106 MM 136 Phase 3 Stage 2 Arm A Iberdomide + Daratumumab + Dexamethasone Q28D USOR 24106 MM 136 Phase 3 Stage 2 Arm B Daratumumab + Bortezomib + Dexamethasone Q21D (C1-8) USOR 24106 MM 136 Phase 3 Stage 2 Arm B Daratumumab Q28D (C9+)
24099	USOR 24099 ALL09 Phase 1 Dexamethasone D-7 to Day –1 USOR 24099 ALL09 Phase 1 VNX-101 + Dexamethasone D0+
23294	USOR 23294 GYN 132 Ph3 Arm 2 Gemcitabine D1,8 Q21D USOR 23294 GYN 132 Ph3 Arm 2 Irinotecan D1,8,15,22 Q42D USOR 23294 GYN 132 Ph3 Arm 2 Pemetrexed Q21D USOR 23294 GYN 132 Ph3 Arm 2 Tisotumab Vedotin Q21D USOR 23294 GYN 132 Ph3 Arm 2 Topotecan D1-5 Q21D USOR 23294 GYN 132 Ph3 Arm 2 Vinorelbine D1,8 Q21D USOR 23294 GYN 132 Ph3 Run-in AND Arm 1 MK-2870 Q14D
22320	USOR 22320 BRE 441 Phase 3 Arm 1 Dato-DXd + Durvalumab Q21D USOR 22320 BRE 441 Phase 3 Arm 2 Pembrolizumab + Gemcitabine + Carboplatin Q21D USOR 22320 BRE 441 Phase 3 Arm 2 Pembrolizumab + Nab-Paclitaxel Q21D USOR 22320 BRE 441 Phase 3 Arm 2 Pembrolizumab + Paclitaxel Q21D

Updated Reference Information

Study Number	Updated Reference Information	Updated Drug Service Order Information	Updated Regimen Instructions	Other Changes
23025	Version 8.0: 06 September 2024.	Updated Drug dose and dosing schedule comments	NA	NA
23189	NA	Updated reconstitution instructions	Added dosing weight instructions	Updated infusion time in IP instructions
23288	NA	Updated preparation/administration instructions	Updated cohort-specific dosing instructions	NA
23076	NA	Updated order of drugs administered. Rearranged drug items under corresponding headers. Added hydration	Updated order of administration comment. Added weight-based dosing	NA
23276	Amendment 2.0: 24 June 2024	NA	NA	NA
21462	Version 6.0: 02 Aug 2024	NA	NA	Updated cycle length to include an additional administration day
20403	Protocol Amendment 5 Version 6.0: 25 April 2024	NA	NA	NA

Study Number	Updated Reference Information	Updated Drug Service Order Information	Updated Regimen Instructions	Other Changes
22042	Amendment 4: 30 MAY 2024	Removed twice daily IP line.	Removed fasting requirement. Added administration instruction.	Added 7 new regimens
23095	Version 4.0: 26 September 2024	Added "Supplied by sponsor"	Adding wording on prophylaxis, observation, double-blind,	Activated 2 new arms
23185	NA	Updated reconstitution instructions	NA	NA
23332	Added Protocol Clarification Memo #2: 14 Oct 2024	Updated reconstitution instructions	Added administration wording	Combined 2 dose builds into 1 build with 2 dose options. Added additional form of administration for AZA (SQ & IV)
21533	NA	Removed Ondansetron premedication	NA	Updated diagnosis code
22302	NA	Added additional form of administration, clarified form reconstitutions	Clarified dose formulation choices	Inactivated closed arm

Study Number	Updated Reference Information	Updated Drug Service Order Information	Updated Regimen Instructions	Other Changes
20408	Protocol Substudy Version 2: 25 August 2023 Protocol Version 5: 25 August 2023	NA	NA	New arm
22002	NA	NA	NA	Inactivated closed arm
22244	NA	NA	NA	New arm