

Overview of FACT Accreditation Process

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FACT Voluntary Accreditation Process

- Overview
- Timeline
- Guidelines for success

Accreditation Overview

Accreditation is based on documented compliance with current Standards

- Submitted documents
- On-site inspection
- Accreditation Committee review

Eligibility (initial) and Renewal Applications

- Demographics; services
- Length of time in operation; presence of required personnel; number of procedures

Compliance Application – “checklist”

- Includes each Standard
- Customized to each specific program or bank
- Requires uploaded documents

International Inspections

Immune effector cell inspections will likely all be in North America for the time being

- Still important to understand that FACT is an international organization and has processes for situations in which a program does not primarily do business in English

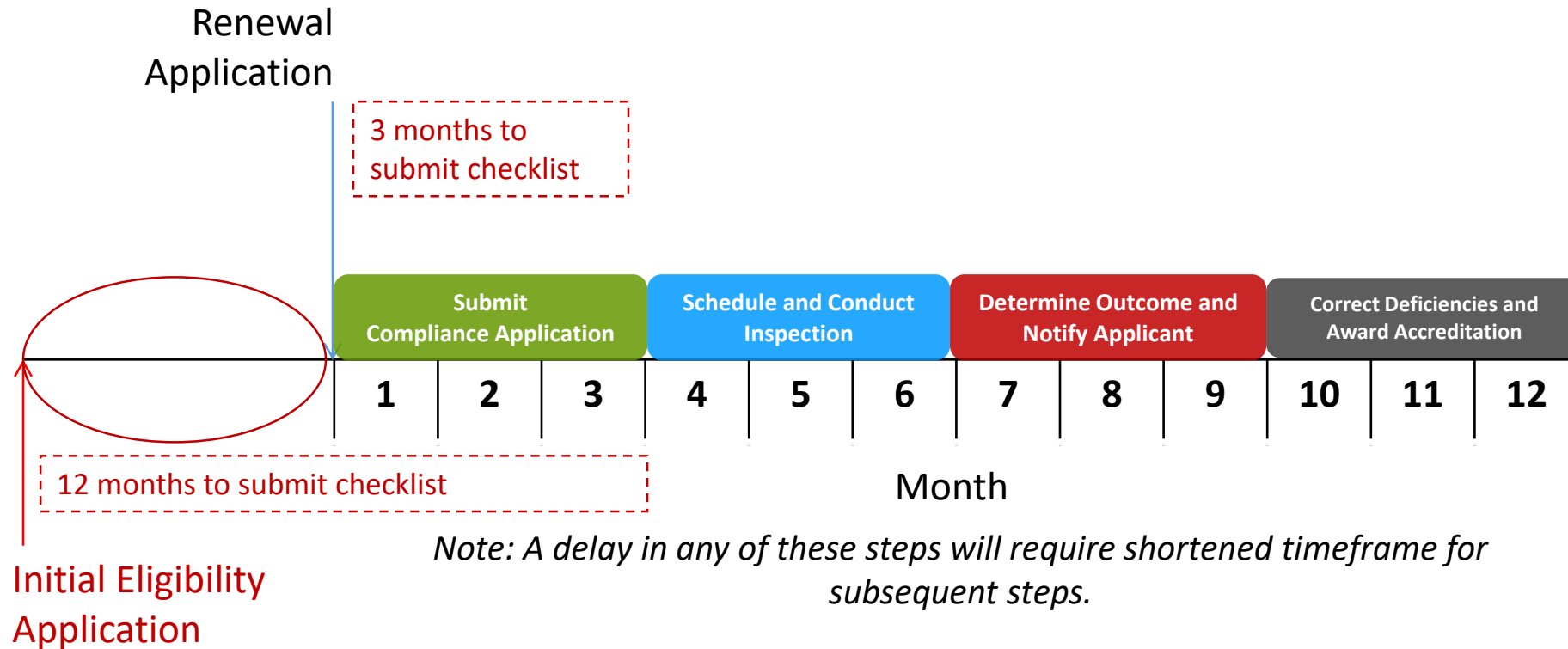
If applicant's primary language is not English, pre-inspection documentation submitted to FACT must be translated or summarized in English

- A document checklist will be created to list what must be submitted in advance of the inspection
- These are documents that are reviewed before the inspection
- FACT does NOT require all documents to be in English for the inspection

Applicants must provide an interpreter to translate/interpret documents for inspector throughout the inspection if English is not the primary language

- NOT necessarily an independent person
- Staff member(s) who are fluent in English can serve as interpreter(s)

Overall Timeline & Steps



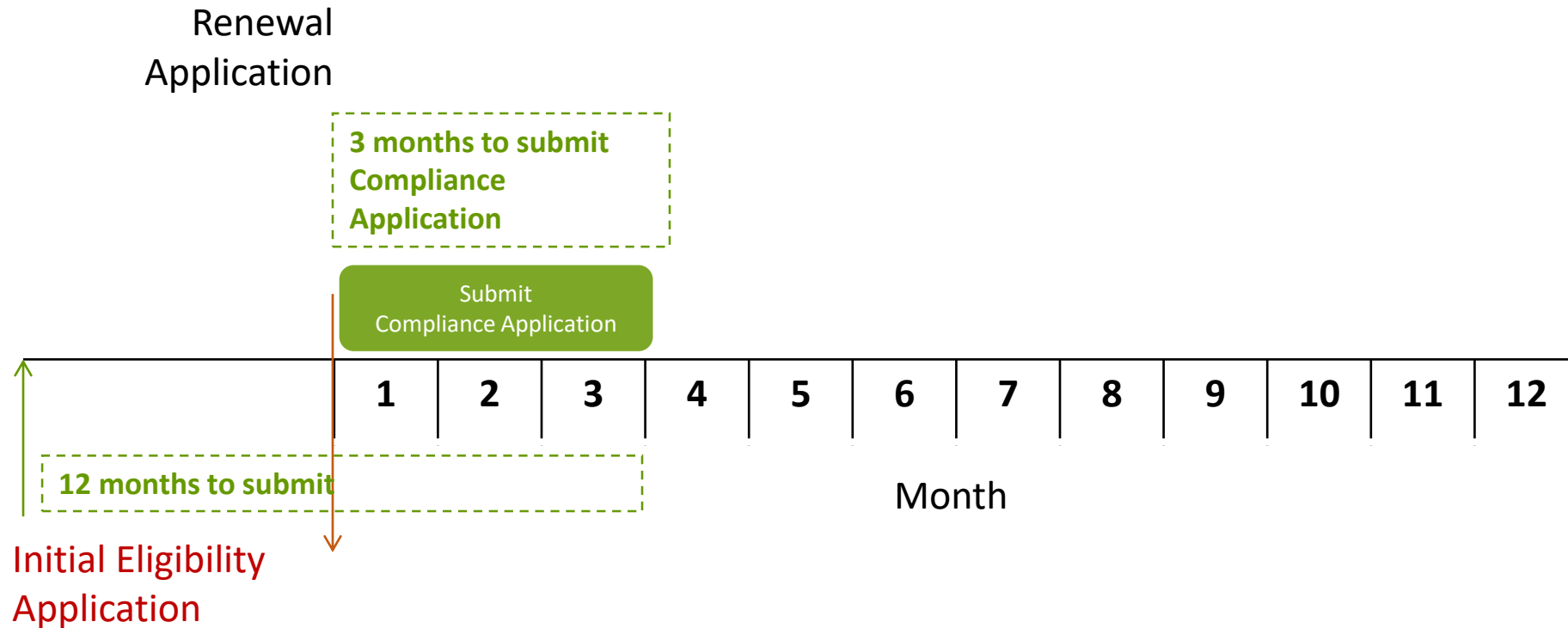
Eligibility Application

- Used to apply for initial accreditation
- Includes a nonrefundable registration fee
- Apply after self determination of eligibility and confirmed organizational commitment
- FACT uses answers to Eligibility Application to:
 - Determine eligibility for accreditation
 - Define accreditation goals based on services
 - Generate the compliance application

Renewal Application

- Renewal Application - similar to Eligibility Application
- Accredited programs notified when to complete as part of annual reporting process after second year of accreditation cycle
- FACT uses renewal application to:
 - Determine continued eligibility for all services
 - Define renewal accreditation goals
 - Note critical changes since last application
 - Generate the Compliance Application

Submission of Compliance Application



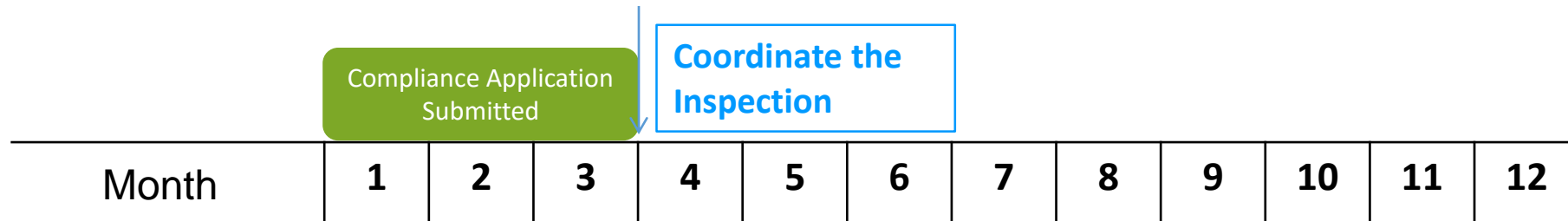
Compliance Application

- Describes the applicant's organization and accreditation goals
 - “Goals” = services performed
- Includes customized checklists created by FACT
 - Customized to applicant's services
 - Minimizes use of “not applicable”
 - Not completely perfect
- Documents applicant's self-assessment of compliance with the Standards
- Requires document uploads for some standards

Submit Online Compliance Checklist By Assigned Deadline

- Initial applicants have 12 months from initial application
 - Expected that more time is necessary to bring documents and processes into compliance
- Renewal applicants have 3 months from notice
 - Should already be in compliance with Standards
 - Be sure to complete gap analysis when new edition of Standards is published
 - Can start renewal preparation early by reviewing Standards requirements, gathering in-date documents, updating organizational chart

Coordination: FACT Office, Applicant, and Inspectors



Accreditation Coordinators

- FACT staff members with specific expertise in standards and accreditation
 - Review applications, inspection reports; summarize reports for Accreditation Committee
- One coordinator assigned to each application to provide consistency
 - Useful resource for inspectors and applicants
 - Can be reached by phone or email
 - Also available after accreditation has been awarded and throughout the accreditation cycle

Inspection Readiness

FACT Accreditation Coordinator confirms applicant's readiness for on-site inspection:

- Reviews compliance application
- Confirms presence, but not adequacy, of required pre-inspection documents, including:
 - ✓ Current medical licenses, board certification
 - ✓ A clear and complete QM Plan that includes all elements
 - ✓ SOP for SOPs
 - ✓ Required informed consent elements
 - ✓ Complete and appropriate label content
 - ✓ Appropriate steps/number of observations in validation plans

Applicant: Choosing the Best Date

- Applicant provides potential inspection dates to FACT
- Key personnel available
- Designated personnel available – tours, translators, transportation
- All sites selected for inspection available
- Not later than six months before expiration date
- Suggest more than one potential date!

Applicant Preparation

Inspection Schedule

- Staff: Knowledgeable personnel accompany each inspector; answer questions; retrieve info
- Tours: All personnel aware of expectations
- Especially important for multiple sites
- Exit interview: Invite other key persons

Room Reservations

- Inspector Work Room
- Initial meeting and Exit Interview room(s)
- Internet Connection (ideally for each inspector)
 - Wireless/wired
 - Conference room computer

Lunch Arrangements

- Often used as working lunch
- Light fare
- Remember the off-site inspectors (if applicable)
- Applicant may wish to offer separate lunch for staff

Logistics

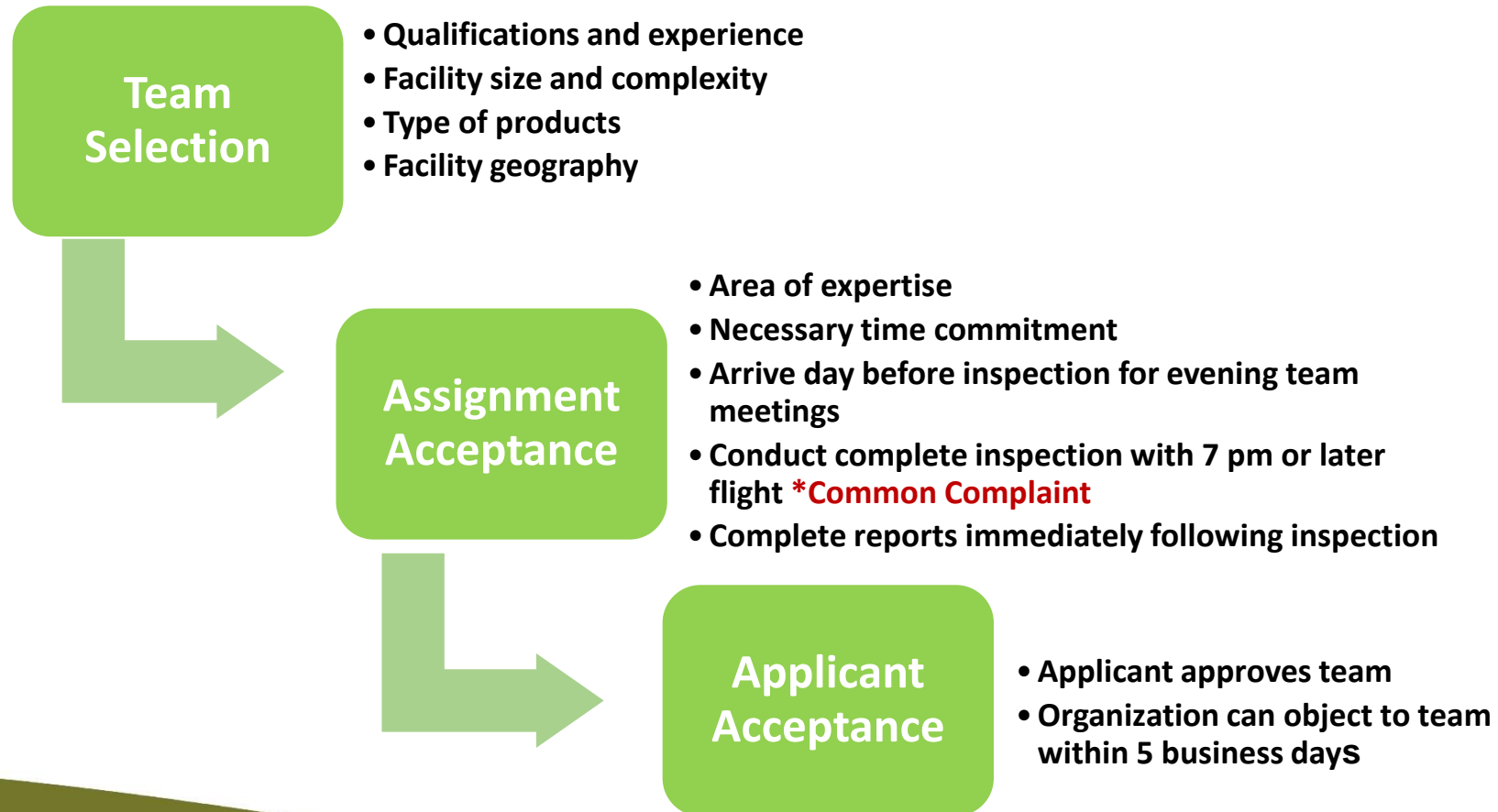
HOTEL

- Recommend for inspectors:
- Convenient
- Reasonable
- Meeting Room available

Transportation

- Arrangements or directions
- Be specific
- Allow for transit time; applicants should inform inspectors

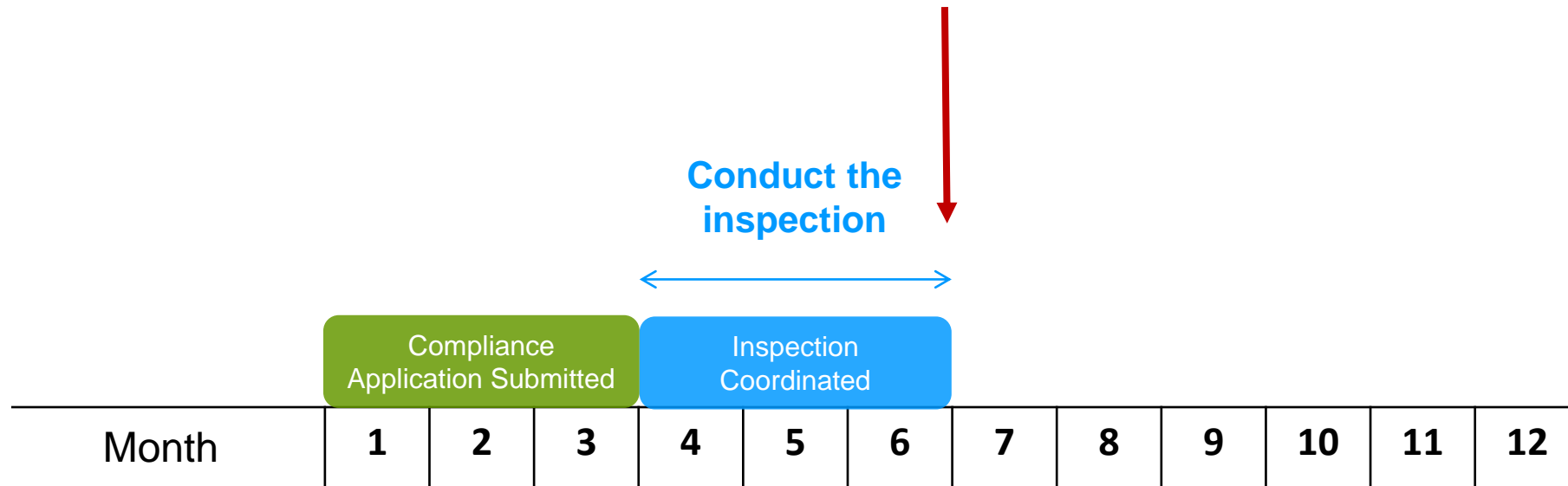
Selecting the Inspection Team



Inspector Conflicts of Interest

- Recuse yourself from inspection
- Potential conflicts
 - Close working/collaborative relationship
 - Competition for referrals, contracts, etc.
 - Non-financial incentives
 - Unfavorable history – employment; grants
- Potential legal implications
 - Applicant and accredited facilities
 - Patients, insurance companies, etc.
 - FACT

On-Site Inspection



Typical Inspection

Repeated
on each
day as
needed
(e.g.,
multiple
sites, cord
blood
banks,
etc.)

- Initial Interview
 - Inspection Team introductions, overview of organization presented by applicant, questions/clarifications
- Facility(ies) Tour
 - Provides confirmation of compliance with several standards, enhances understanding of general organization workflow
 - Brief interview of staff and/or chance to observe
- Working Lunch
- Document Review
 - Review of documentation not previously submitted
- Exit Interview
 - A brief summary of the inspection, a closure to the day

Initial Interview

- Purpose: To introduce inspectors, applicant personnel, and the applicant organization
- Applicant presents introductory information:
 - History of the organization; power point slides are good idea; provide copies to team
 - Services provided
 - Overview of organizational chart – emphasize unusual
 - Include off-site facilities
 - Overview of Quality Management Plan(s)
- The inspection team introduces themselves, role on the inspection team, and “day job”
- Inspection team reviews schedule for the inspection day; verify appropriateness
- Inspection team may request additional documentation

Tours

- Purposes:
 - Assessment of facilities – Inspectors: be observant!
 - Confirm compliance with many standards and understand the organization's general workflow
 - Interact with staff; ask questions about policies or procedures
 - Observe procedures. Inspectors may request mock procedure
- May be conducted in the morning or afternoon, depends on scheduled procedures, preferences, availability
- First rule of tours: Every place must be seen; not everyone needs to see everything
- Be careful not to be critical of staff in front of patients or families

What makes a good inspection?

Preparation!

Applicant

- Begin early
- Read Standards carefully
- Thoroughly complete Compliance Application
 - Note **exactly** where inspector can find documentation of compliance for each question
- Schedule inspection on date key personnel will be available

Inspector

- Review documentation ahead of time
 - *Before* getting on the plane!
 - Follow-up with applicant regarding questions
 - Mark compliant Standards if possible
 - Make notes to check on site
- Attend pre-inspection team meetings and conference calls

Applicant Preparation: Checklist

Complete Compliance Application

Mock inspection/
self-assessment tool
first

Be honest and
compulsive

Be careful with “Not
applicable”

Address Deficiencies

Are you
documenting
compliance?

Revise or add SOPs,
forms, and
worksheets to
include necessary
documentation

Submit Compliance
Application

Organize Documents

Order SOPs by
Standards

Highlight SOP
section/attach
documentation
pertaining to
Standard

Indicate location on
the Compliance
Application

Applicants: What to Do . . .

- Be courteous, punctual, and helpful
- Have at least one staff member appointed to each inspector
- Be conscious of demands on inspectors
- Promptly gather additional documentation requested

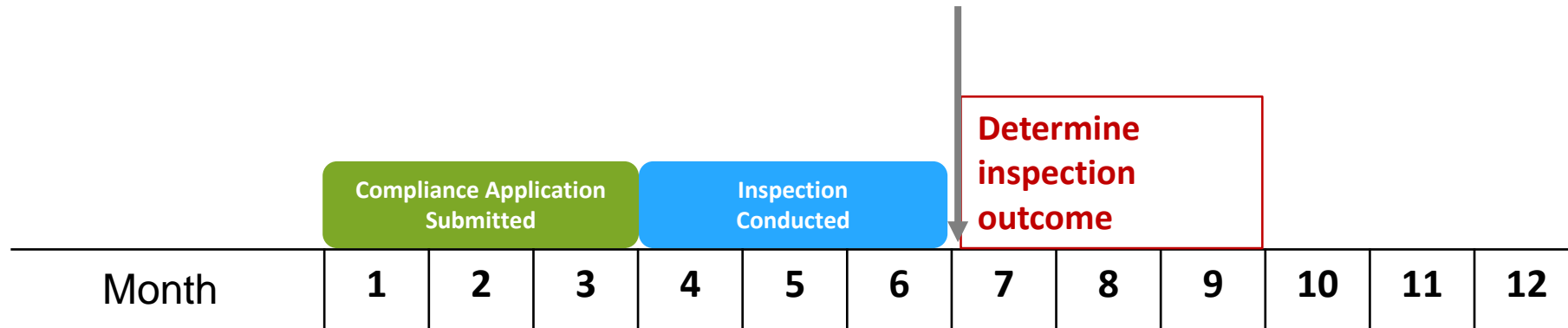
Applicants: What Not to Do ...

- Plan to show inspectors exclusively electronic records
- Assume that whatever passed the last inspection will be sufficient
- Expect to know the outcome of the inspection before the inspection team leaves
- Argue with the inspectors

Closing the Inspection

- Inspection team will have a closed session to review findings and prepare for exit interview
 - The inspector may request a private session with the Program Director if needed
- Exit interview:
 - Summation
 - Applicant may invite significant personnel as desired
 - Should be no surprises at interview or in final report
- Exit interview process will be explained later today

Inspection and Accreditation Outcome

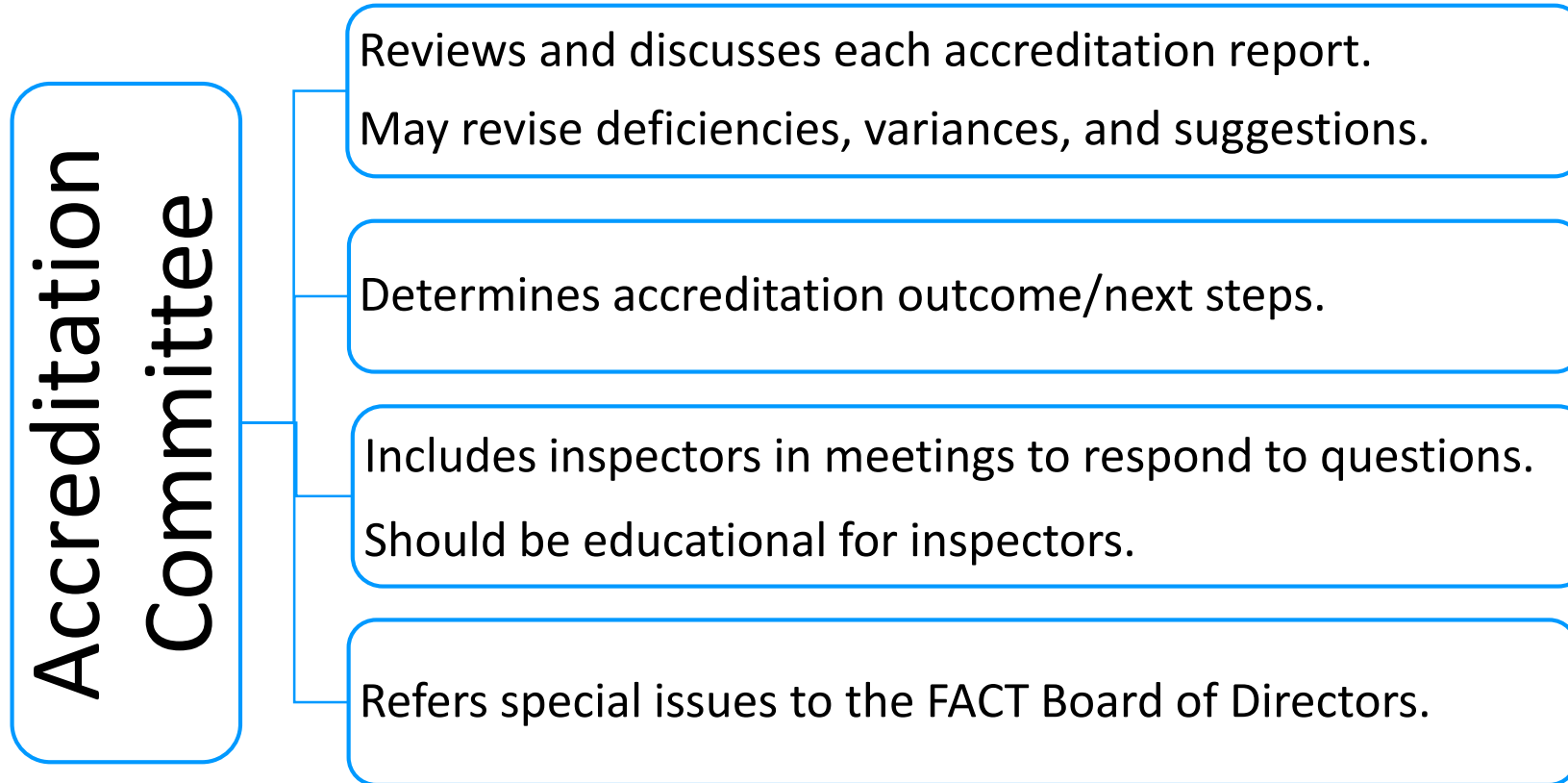


Inspection Report

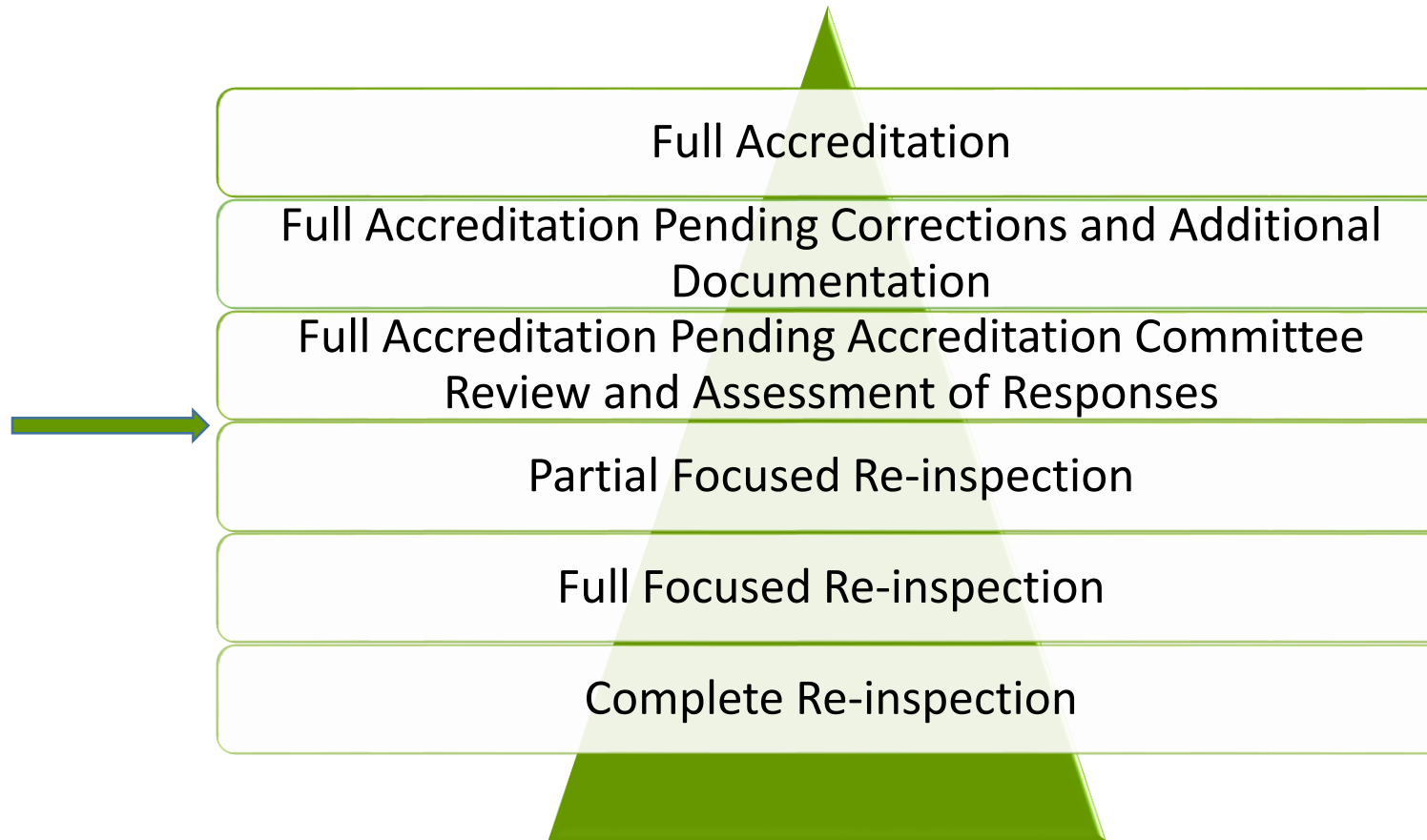
- Each inspector writes report; submits online within three days of on-site inspection.
- Each inspector reviews each standard marked “not compliant” and clearly describes the deficiency.
- Team leader reviews final report and submits online to the FACT office within two weeks of inspection.
- Additional details will be provided later today.
- Sample deficiency:

B7.1.1	The Clinical Program shall provide information regarding the risks and benefits of the proposed cellular therapy.
Deficiency:	The informed consent form includes risks and benefits of cellular therapy, but it does not explain what cytokine release syndrome is.
Required Response:	The program must submit a revised informed consent form that describes, or a process for verbally explaining, cytokine release syndrome.

Next Steps...



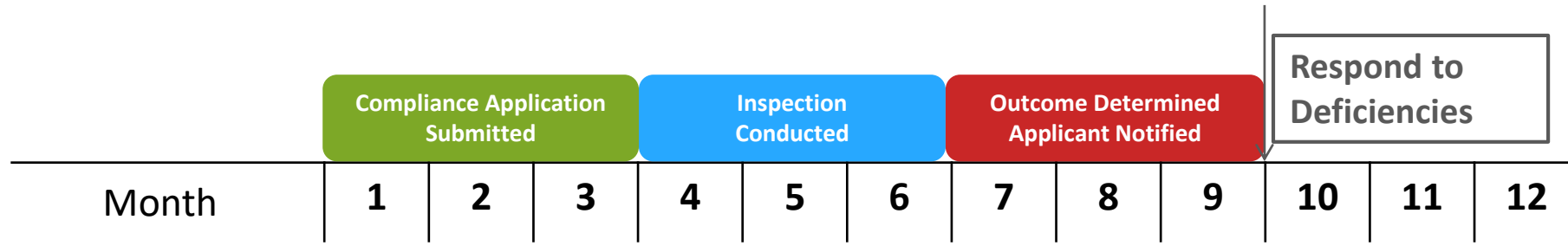
Potential Outcomes



Notification of Outcome

- Key personnel identified in accreditation portal receive email notification
- Letter explains overall results
- Accreditation report includes each deficiency, variance, and suggestion
- Accreditation report includes for each deficiency:
 - Applicable standard number
 - Explanation of deficiency
 - Required responses
 - Response timeline

Responding to Deficiencies



Final Report and Response

- Before receipt of final report, applicant should not:
 - Submit responses
 - Make changes they would not otherwise make
- Upon receipt of final report, applicants should:
 - Submit response for each deficiency within the specified period of time
 - Consult with Accreditation Coordinator as needed

Respond to Deficiencies

- For each deficiency:
 - Explain how the deficiency has been corrected
 - Provide documentation of implemented correction
 - If deficiency requires significant change, applicant may be asked to submit a corrective action plan and agree to provide interim data
- Provide explanation for variances
- Deficiencies generally must be corrected within 3 months
- If process is not complete within 12 months:
 - Program may be required to reapply
 - Renewal applicants may be suspended
- Reinspections may be allowed 16 months to complete process

Example Response to Deficiency

Applicant Response	The informed consent form was revised to explain the symptoms and risks of cytokine release syndrome.
Attachments	Revised form: CT.006.04 Informed Consent for CAR-T Cellular Therapy. Revised section VII.A is highlighted. New version implemented 04/04/2016.

Re-Inspection

- Return to site to verify significant deficiencies have been corrected
- Opportunity for applicant to show improvement
- May be original or new inspector
 - Depending on preferences of the organization or inspector or determination of the Accreditation Committee
- May be focused
 - Inspect checklist items where issues identified on initial visit
- May be complete reinspection

Accreditation Awarded!



Once all Standards have been met:

- Director will receive a letter and certificate indicating FACT accreditation; which facilities; which services
- FACT accreditation is for a period of three years
- Renewal process begins two years from accreditation date

	Compliance Application Submitted			Inspection Conducted			Outcome Determined Applicant Notified			Deficiencies Corrected Accreditation Awarded		
Month	1	2	3	4	5	6	7	8	9	10	11	12

On-Site Inspection Evaluation

- Send feedback on inspection process to FACT office
- Goal is to continue to improve process
- Evaluations are kept confidential
- The evaluation does not impact the accreditation outcome
 - Separate committees and staff

Accreditation Suspension or Termination

Suspension

- Not accredited
- Removed from website pending resolution of issue
- Accreditation reinstated without change in expiration date when issue is resolved

Termination

- Accreditation revoked
- Completion of entire accreditation process required to regain accredited status

Typical Causes

- **Extensive delays past accreditation timelines caused by the applicant**
- **Significant deficiencies that take long periods of time to correct**

Resources

- Process Overview

<http://www.factwebsite.org/accreditationprocess/>

- Applicant Guidelines

http://www.factwebsite.org/Accreditation_Process/CB_Applicant_Guidelines.aspx

- Maintaining Accreditation

http://www.factwebsite.org/Accreditation_Process/Maintaining_Accreditation.aspx

Thank you!